NWOS
Northwest Orthopaedic Specialists, P.S.
The Orthopaedic Surgery Center

MAY - 9 2005

May 6, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P
P.O. Box 8014,
Baltimore, MD21244-8014

Re: File code CMS-1478-IFC

Dear Dr. McClellan:

I appreciate the chance to comment on proposed changes to ASC approved procedures. As an administrative director for a freestanding orthopedic surgery center, I would find it extremely valuable to include the following spine surgery codes on the approved ASC list:

63030
63035
63042
63047
63048

In our practice we have been performing many of these procedures for outpatients for the past year. We have saved the commercial insurance carriers thousands of dollars and provided their patients with a much more pleasant experience in our ASC as compared to the hospitals inpatient facilities. We expect that Medicare could also realize substantial savings from having them performed in a freestanding ASC. We recognize that the majority of spine surgeons still perform these procedures in an inpatient setting, but as technology and the advancement of minimally invasive surgery have progressed, the approved codes for ASC have not always kept pace.

We believe that adding these codes to the approved ASC list will increase access to quality care and help control costs.

Sincerely,

Edward M. Webster
Administrative Director
The Orthopaedic Surgery Center

cc: John Shuster, M.D.

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MAY 27 2005

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Henry Alder
Director
Reimbursement & Healthcare Economics
4545 Creek Road, ML 90
Cincinnati, Ohio 45242
(513) 337-3201

May 20, 2005

The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
Box 8017
Baltimore, MD 21244-8017

RE: CMS-1478-IFC: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures.

On behalf of Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company, we are pleased to submit comments on the Interim Final Rule: "Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures," published in the Federal Register on May 4, 2005. We wish to comment on the Proposed Addition of CPT 46947 – Hemorrhoidopexy by stapling to the ASC list (page 23709).

We recommend reassigning CPT code 46947 from payment group 3 to payment group 7, 8 or 9. We believe that Medicare medical staff omitted the cost of the surgical supplies when they assigned CPT 46947 to payment group 3. On page 23700, of the May 4, 2005 Federal Register, the rationale for assignment of CPT 46947 is *"Hemorrhoidopexy by stapling is a new procedure for 2005, and our medical staff believe that the procedure is of a complexity substantially similar to the other procedures (for example, CPT code 46257, hemorrhoidectomy, internal and external, with fissurectomy) assigned to payment group 3, and so we will add CPT code 46947 to the ASC list and will assign it to payment group 3."*

Hemorrhoidopexy by stapling requires the use of a unique surgical supply called a Hemorrhoidal Circular stapler, which costs $389. (The list price for the Hemorrhoidal Circular Stapler from the EES Price List is enclosed.) The total cost for stapled hemorrhoidopexy procedure at the Cleveland Clinic is calculated to be $1898; the calculation is also enclosed. We recommend that CPT 46947 be assigned to Payment Group 7, 8 or 9 so that the payment compensates the ASC adequately for the surgical supply and to ensure the payment is consistent with hospital outpatient reimbursement. The payment for CPT 46947 under the HOPPS is $1321.19. It is important to have consistent payment rates between the hospital outpatient and the ASC so that reimbursement does not influence the clinical setting for the procedure. This is consistent with the January 2003 OIG study that said, *"There should be greater parity of payments for services performed in an outpatient setting and those performed in an ASC."*(Federal Register, p. 23692.)

Ethicon Endo-Surgery, Inc. markets the Proximate PPH stapler for stapled hemorrhoidopexy. Stapled Hemorrhoidopexy can replace open hemorrhoidectomy for certain patients with Grade 3 and Grade 4 hemorrhoids. We are enclosing a booklet describing the Stapled Hemorrhoidopexy procedure, the PPH surgical stapler and the procedure kit components that are required for stapled hemorrhoidopexy.

Center for Medicare and Medicaid Services
CMS-1478-IFC
May 20, 2005

Thank you for your consideration of our comments and recommendations. We look forward to continuing to work with you and your staff in resolving these complex issues.

Sincerely,

Henry Alder
Director – Reimbursement & Healthcare Economics

Enclosures – Procedure for Prolapse and Hemorrhoids

cc. Kathy Buto
Greg White
Joan Sanow
Bob Cereghino

Price
2005
List

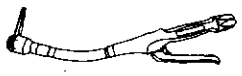
ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Conventional Surgical Products

Circular Staplers

PROXIMATE ILS Curved Intraluminal Staplers – Detachable Head

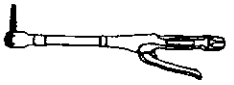
CDH



CDH21	Circular Stapler, curved, 21mm	$1,890.29	3
CDH25	Circular Stapler, curved, 25mm	$1,890.29	3
CDH29	Circular Stapler, curved, 29mm	$1,890.29	3
CDH33	Circular Stapler, curved, 33mm	$1,890.29	3
CSS	ENDOPATH ILS Circular Sizer Set for ILS circular staplers. Includes: (1) 25mm, (1) 29mm, (1) 33mm sizes	$398.00	1

PROXIMATE ILS Straight Intraluminal Staplers – Detachable Head

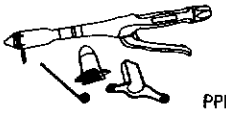
SDH



SDH21	Circular Stapler, Straight, 21mm	$1,644.51	3
SDH25	Circular Stapler, Straight, 25mm	$1,644.51	3
SDH29	Circular Stapler, Straight, 29mm	$1,644.51	3
SDH33	Circular Stapler, Straight, 33mm	$1,644.51	3

Hemorrhoidal Circular Staplers*

PROXIMATE HCS - Procedure for Prolapse and Hemorrhoids (PPH) Set*



PPH03

PPH03	PROXIMATE PPH Procedure for Prolapse and Hemorrhoids Set	$1,167.00	3

Not available through distributors

$389 ea

Addendum to Update of Ambulatory Surgical Center—Total Cost

According to Tony Senagore, MD, colorectal surgeon at the Cleveland Clinic, TSI is used to calculate direct cost inputs such as labor, supplies and depreciation for hospital outpatient department stapled hemorrhoidopexy procedures. Direct Cost is $1139 including the cost of the PPH Set. Indirect cost including utilities, cost of debt is calculated to be 40% of total cost.

Total Cost for PPH = Direct Cost + Indirect Cost

Direct Cost = $1139 (includes cost for PPH set)

Indirect Cost = 40% of Total Cost

Calculation of Total Cost at the Cleveland Clinic)
Total Cost = $1139 + 0.40 Total Cost
Total Cost = $1898

Source: Tony Senagore, MD, Cleveland Clinic, 2004

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MAY 27 2005

Surgery Center Plus,℠ Inc.
7430 North Shadeland Avenue, Suite 100
Indianapolis, Indiana 46250

Department of Health and Human Services
CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: New Code's group assignment is wrong
CPT 46957 Hemorrhoidopexy by Stapling
Payment Group 3, $505
Effective date of July 1, 2005

Dear Medicare:

Our facility is writing to request you change the Group assignment for the new CPT code 46957 for Ambulatory Centers from 3 to 8.

Hemorrhoidopexy by stapling is a new procedure for 2005. When it was added to the CPT book, it was approved with a facility payment level of $1321 when performed at a hospital. Recently Medicare has approved for ASC's but allowed it only as a Group 3. This allowance does not actualize the cost of the equipment.

Our medical staff and we believe that this procedure is of a complexity substantially similar to procedure for "hemorrhoidectomy, internal and external, with fissurectomy" payer under Group 3. However, CPT 46957, requires a stapler that cost the ASC $389 plus additional supplies of $150. In addition, our clinical staff cost for the procedure is approximately $150. As you are aware, as an ASC we are paid globally and are not able to bill separately for supplies. Therefore, our cost, before we start the procedure is already higher than your proposed allowed amount.

There are two primary elements in the cost of performing a surgical procedure. These costs are the cost of the physician's professional services in performing the procedure and the cost of items and services furnished by the facility where the procedure is performed, such as surgical supplies and equipment, and nursing services. It does not appear that the costs for these procedures were calculated.

Taking the above into consideration one concludes that CPT 46957 should be paid under Group 7,8 or 9, and not under Group 3. Failure to make this correction basically negates the presence of the new code on the ASC approved listing. Please reconsider it's group.

Sincerely,

James W. Hansen, Administrator

317/841-8005 Fax: 317/577-7538

Piedmont Neurosurgical Group, P.A.

MAY 27 2005

109 Montgomery Drive
Anderson, S.C. 29621
Telephone 864-224-5700

Michael N. Bucci, M.D., F.A.C.S.
Aaron C. MacDonald, M.D., F.A.C.S.
Christie B. Mina, M.D.

3 St. Francis Dr. Suite 330
Greenville, SC 29601
Telephone: 864-220-4263

May 12, 2005

Mr. Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid
Department of Health and Human Services
Attention: CMS-[redacted]P, P.O. Box 8014
Baltimore, MD 21244-8014

RE: File Code CMS-1478-IFC

Dear Dr. McClellan:

Thank you for the opportunity to express my opinion regarding the proposed changes to ASC approved procedures. For the past twelve years, my group and I have been performing outpatient lumbar spine surgery for the following codes on non-Medicare patients: 63030, 63035, 63042, 63047, and 63048. These are safe procedures which can be performed safely as an outpatient, and we have had no undo or adverse complications with this practice approach. This can certainly be extrapolated to the Medicare age population patient who happens to be in good health and can tolerate an outpatient surgery.

Therefore, we respectfully request that you consider including these surgical procedures as an outpatient. This would certainly save the government a great deal of money and avoid unnecessary overnight hospitalizations in a vast number of patients.

Thank you very much for your time in this matter.

Sincerely yours,

Michael N. Bucci, M.D., F.A.C.S.
Clinical Assistant Professor/MUSC

MNB/pwc

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JUN - 3 2005

Coalition For The Advancement Of Brachytherapy
660 Pennsylvania Avenue, S.E.
Suite 201
Washington, D.C. 20003
(202) 548-2307
Fax: (202) 547-4658

June 3, 2005

Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule (CMS-1478-IFC)

Dear Dr. McClellan:

The Coalition for the Advancement of Brachytherapy (CAB)[1] would like to provide comments regarding the Centers for Medicare and Medicaid Services' (CMS) interim final rule that updates the list of covered procedures provided in an ambulatory surgical center (ASC), which was published in the May 4, 2005 Federal Register (see attachment 1).

CMS has made significant changes to the list of covered services performed in the ASC setting. CAB is pleased that CMS added four (4) brachytherapy codes to the list of ASC covered services. We agree with your decision that uterine and breast brachytherapy are appropriate services for the ASC setting. Further, we appreciate the clarification in the interim final rule that payment for brachytherapy procedures does not include the costs of the brachytherapy sources (seeds), which are paid separately under the Medicare Physician Fee Schedule. Our recommendations to CMS are summarized below:

- CMS should assign CPT 19298 to ASC Payment Group 9 at $1,339
- CMS should add CPT 19297 to the list of ASC Covered Services and assign this procedure to ASC Payment Group 9
- CMS should clarify that breast brachytherapy catheters may be paid separately, and in addition to the procedure, under the Medicare Physician Fee Schedule

[1] The Coalition for the Advancement of Brachytherapy was organized in 2001 and is composed of the leading developers, manufacturers, and suppliers of brachytherapy devices, sources, and supplies. CAB's mission is to work for improved patient care by assisting federal and state agencies in developing reimbursement and regulatory policies to accurately reflect the important clinical benefits of brachytherapy. Such reimbursement policies will support high quality and cost-effective care. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members and it is our mission to work for improved care for patients with cancer.

Analysis Of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of this Interim Final Rule With Comment Period

I. Additions to the List of ASC Services—CPT 19296 & 19298

The Coalition for the Advancement of Brachytherapy is appreciative that CMS added two of the three new breast brachytherapy codes to the list of ASC covered services. They are:

- 19296 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy

- 19298 Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance

CAB recommended that both codes be placed in ASC Payment Group 9, however, CMS assigned CPT code 19296 to Payment Group 9, and CPT 19298 to Payment Group 1.

The January 2003 report of the Office of the Inspector General (OIG) entitled "Payments for Procedures in Outpatient Departments and Ambulatory Surgical Centers" concluded that there should be a greater parity of payment for services performed in an outpatient setting and those performed in ASCs. Under the Hospital Outpatient Prospective Payment System both codes are assigned to APC 1524 with a payment of $3,250 because they are similar both clinically and with respect to resource utilization. Payment of $333.00 for CPT 19298 does not cover the facility costs of this procedure and creates a large disparity of payment for HDR brachytherapy performed in the ASC setting from services provided in the hospital outpatient setting. CMS should reassign CPT 19298 to ASC Payment Group 9 at $1,339. The proposed payment of $333.00 will discourage utilization of HDR breast brachytherapy in the ASC setting and will not provide for appropriate reimbursement of the cost to provide this care.

Partial breast irradiation with HDR brachytherapy requires the surgical insertion of catheter(s) into the breast. CPT 19296 involves a single balloon catheter inserted into the lumpectomy cavity and inflated prior to radiation therapy. CPT 19298 involves interstitial placement of 12 to 36 catheters surrounding the lumpectomy cavity prior to radiation therapy. (See attachment 2, April 2005 AMA "CPT Assistant" for more clinical detail). CPT 19296 and 19298 are procedures that are similar clinically and require similar resource consumption. Technical costs include the facility time, technical staff time, anesthesia and general supplies. Both procedures can be safely performed in the ASC.

CAB recommends that CPT 19298 should be assigned to ASC Payment Group 9.

II. Additions to the List of ASC Services—CPT 19297

In correspondence dated January 14, 2005, CAB recommended that CPT code 19297 be added to the list of ASC covered services and assigned to Payment Group 9 as this procedure is similar clinically to CPT 55859 prostate brachytherapy needle placement.

- 19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy)

CMS did not include CPT 19297 on the updated list of ASC services and stated that this was an "add-on" procedure that is included in another procedure and not performed on its own. This procedure is exactly the same as CPT 19296 except that it is performed on the same day as the partial mastectomy, and 19296 is performed on a later date after the partial mastectomy. Although the CPT description of 19297 lists this procedure as an "add on" procedure, this procedure is unique and distinct from the partial mastectomy primary procedure. (See attachment 2, April 2005 AMA "CPT Assistant" for more clinical detail). The primary procedures are approved ASC procedures, and 19297 can be safely performed in the ASC as a secondary procedure to the primary surgery, just as in the hospital outpatient department. Costs are simliar as the resources for this procedure, including facility time, staff, anesthesia and general supplies are equivalent to 19296.

CAB recommends that CPT 19297 should be added to the list of ASC covered services and assigned to ASC Payment Group 9. This "add-on" procedure is separate and distinct from the partial mastectomy and the facility costs associated with CPT 19297 are significant.

III. Clarification of Separate Payment for Brachytherapy Catheters—A4649

CAB understands that brachytherapy payment policy is complex. We appreciate the clarification in the interim final rule that payment for brachytherapy procedures does not include the costs of the brachytherapy sources (seeds).

CAB recommends that CMS make clear that brachytherapy catheter(s) are also paid separately as are other supplies utilized in brachytherapy procedures. Catheters should be purchased by the surgeon and billed by the surgeon using A4649. The breast brachytherapy catheter(s) range in cost from $2,500 to $3,500 per patient, and are clearly not covered supplies under the ASC fee schedule. The catheters would be purchased by the physician and billed separately under the Medicare Physician Fee Schedule in addition to the procedure following the same payment methodology as brachytherapy sources.

CAB requests that CMS clarify in the ASC rule that breast brachytherapy catheters may be coded as A4649 *Surgical supply, miscellaneous* and be billed by the surgeon and paid separately under the Medicare Part B Physician Fee Schedule.

Brachytherapy offers important cancer therapies to Medicare patients. Appropriate payment for brachytherapy procedures and sources will ensure that Medicare beneficiaries have full access to high quality cancer treatment in an ambulatory surgical center. Thank you in advance for your consideration of our recommendations. CAB welcomes the opportunity to meet with you to further discuss our recommendations. If you require additional information or have questions, please contact Wendy Smith Fuss, M.P.H. at (703) 534-7979.

Sincerely,

Michael Krachon
Chair

Raymond Horn
Vice-Chair

Attachment 1

Coalition for the Advancement of Brachytherapy (CAB)

The Coalition for the Advancement of Brachytherapy (CAB) is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB members have dedicated significant resources to the research, development and clinical use of brachytherapy, including the treatment of prostate cancer and other types of cancers as well as vascular disease. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members.

CAB Member Companies

C.R. Bard Inc.
Draximage, Inc.
MDS Nordion
Mentor Corporation
North American Scientific, Inc.
Nucletron Corp.
Oncura
Pro-Qura
Proxima Therapeutics, Inc.
SIRTeX Medical, Inc.
Theragenics Corporation
Varian Medical Systems
Xoft microTube

CAB Advisory Board

American Brachytherapy Society
American College of Radiation Oncology
Association for Freestanding Radiation Oncology Centers
Society for Radiation Oncology Administrators

AMA press

April 2005 Volume 15, Issue 4

American Medical Association

Physicians dedicated to the health of America

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ATTACHMENT 2

Your Practical Guide to Current Coding

At Issue This Month

New Vaccine Administration Procedure Codes

In the pediatric population, the delivery of immunizations is an inherently different service than it is in the adult population. Children are given some 25 recommended and or mandated vaccines before the age of 18, the majority of which are administered during early childhood years when reactions can be more frequent and more severe. Children react differently to vaccines due to the physiologic differences inherent in their developing brains, which may cause them to react with neurological events such as seizures and sequelae of an encephalopathic nature.

Coding Communication: Changes to the Integumentary, Breast Section

Breast cancer continues to surface as a top national health concern. It ranks number 1 in occurrence and number 2 in death among women. In recent years, many significant scientific strides have been made in the treatment of this disease, prompting revisions to the CPT codebook to accurately describe the advancements. This coding update focuses on the new guidelines added to the breast excision subsection, the one revised breast excision code, and the three new codes that describe the advancements in brachytherapy treatment of breast cancer within the breast introduction subsection.

Some diagnostic modalities used to detect breast cancer may include a diagnostic mammogram, ultrasonography, magnetic resonance imaging (MRI), fine-needle aspiration, core biopsy, or surgical biopsy. Treatment plans can include a local therapy approach and a systemic therapy approach. A local therapy approach includes surgery (eg, breast-conserving surgery, mastectomy), radiation therapy (eg, internal or implant radiation, external radiation), or breast reconstruction (eg, implant or tissue transfer). A systemic therapy approach includes chemotherapy, or hormonal, or biological therapy.

Within the structural layout of the CPT codebook, breast procedures are classified as a subsection of the integumentary system. Anatomically, the breasts are positioned over the pectoral muscles and are attached with connective issue (fascia). Breast tissue consists of nipple, areola, and skin overlying connective tissues and fat, and ducts that allow the excretion of milk. The codes in the breast section of the codebook follow the following familiar format.

- Incision: 19000-19030
- Excision: 19100-19272
- Introduction: 19290-19295
- Repair and/or Reconstruction: 19316-19396
- Other: 19499

In *CPT 2005*, new introductory text was added to the integumentary breast excision subsection to clarify the appropriate reporting of breast biopsies, partial mastectomy, total mastectomy, and excision or resection of chest wall tumors. The following information will help coding professionals select the appropriate code from the breast section.

Specify What Is Included in "Excisional Surgery"

Excisional breast surgery includes certain biopsy procedures, removal of cysts or other benign or malignant tumors or lesions (eg, ductal abnormalities), and the surgical treatment of breast and chest wall malignancies. Biopsy procedures may be percutaneous or open, and they involve the removal of differing amounts of tissue for diagnosis.

Distinguish a Biopsy From an Open Excision

Breast biopsies are reported using codes 19100-19103 and include percutaneous and open biopsies. Breast biopsies may also include the use of image guidance and/or the use of core needle or other biopsy devices (not including fine needle).

The open excision of breast lesions (eg, lesions of the breast ducts, cysts, benign or malignant tumors) is reported using codes 19110-19126. It is important to note that the adequacy of surgical margins are not specifically considered and may include preoperative placement of radiological markers (eg, guide wire, clip).

Distinguish Partial Mastectomy

Partial mastectomy procedures (eg, lumpectomy, tylectomy, quadrantectomy, or segmentectomy) describe open excisions of breast tissue and include specific attention to adequate surgical margins surrounding the breast mass or lesion.

Partial mastectomy procedures are reported using codes 19160 and 19162, as appropriate.

Specify Total Mastectomy and Its Synonyms

Total mastectomy procedures include simple mastectomy, complete mastectomy, subcutaneous mastectomy, modified radical mastectomy, radical mastectomy, and more extended procedures (eg, Urban type operation). Total mastectomy procedures are reported with codes 19180, 19182, 19200, 19220, or 19240, as appropriate.

Clarify Chest Wall Tumors

Excisions or resections for chest wall tumors including ribs, with or without reconstruction, with or without mediastinal lymphadenectomy, are reported using codes 19260, 19271, or 19272, as appropriate. Codes 19260-19272 are not restricted to breast tumors and are used to report resections of chest wall tumors originating from any chest wall component.

It is important to note that code *19160, Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy*, was revised for *CPT 2005*. The revisions include alternative terms in the descriptor (eg, lumpectomy, tylectomy, quadrantectomy, and segmentectomy) used for partial mastectomy. The inclusion of these terms in the descriptor language of this code clarifies that they are interchangeable with the term *partial mastectomy*.

Additionally, a new cross-reference was added after code *19162, Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary, lymphadenectomy*, to direct users to codes 19296 through 19298 for placement of radiotherapy afterloading balloon/brachytherapy catheters.

Lastly, three new codes were added to the integumentary breast introduction subsection to describe radiotherapy catheter placement and subsequent catheter removal for interstitial radioelement application in the breast following partial mastectomy. They are as follows:

19296 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy

+19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)

19298 Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance

Code 19296 and add-on code 19297 describe interstitial radioelement application catheter placement for radiotherapy afterloading following a partial mastectomy. Code 19296 should be reported when the catheter is placed on a separate date from the partial mastectomy. Add-on code 19297 should be reported when the catheter is placed after the partial mastectomy during the same operative session (concurrent). A parenthetical note was added after code 19297 that directs users to report code 19297 in conjunction with the concurrently performed partial mastectomy code (ie, 19160 or 19162). Code 19298 describes placement of catheters for radiotherapy afterloading brachytherapy following a partial mastectomy. Code 19298 is reported whether the catheters are placed at the time of or subsequent to the partial mastectomy.

To help further clarify the usage and intent of the new breast brachytherapy codes, consider the following intra-service work associated with the following codes.

Code 19296

With the patient under appropriate anesthesia, the lumpectomy site and the remaining breast tissue are examined by the physician to ensure adequate tissue for the radiotherapy afterloading balloon catheter to be securely positioned. The surgeon confirms that the site is appropriate (not too close to the sternum or in the axillary tail of the breast). Next, the surgeon confirms that the cavity has been kept open with only the subcutaneous and top skin layer closed. A skin spacing of 5 to 7 mm between the skin and lumpectomy cavity to protect the skin from radiation damage is confirmed. Using either a sterile ruler or imaging guidance, the size and shape of the lumpectomy cavity are evaluated to determine the appropriate technique for the implantation of the catheter. Prior to insertion, the selected balloon catheter is tested by inflating it with a saline solution. The symmetry and integrity of the balloon is assessed and the balloon is deflated.

Next, a separate "stab-like" incision is made near the lumpectomy incision. Through this incision, a trocar is placed to create a separate pathway to the lumpectomy cavity. Fluid that may have accumulated in the cavity is drained. The catheter is inserted into the lumpectomy cavity via this separate pathway. The balloon catheter is inflated with saline and contrast agent to allow the surrounding tissue to conform to the balloon element of the balloon.

The surgeon monitors the amount of fluid during inflation to ensure that the balloon element is appropriately positioned in the lumpectomy cavity for the correct radiation dosimetry, previously supplied by the radiation oncologist. The 5- to 7- mm skin spacing between the cavity and skin is reconfirmed to ensure that it has remained intact. The surgeon confirms conformance of the cavity to the balloon element of the radiotherapy afterloading balloon catheter. The surgeon verifies the placement and integrity of the radiotherapy afterloading balloon catheter after inflation with the saline and contrast agent. Having verified that the radiotherapy afterloading balloon element of the catheter is secure and appropriately placed, the surgeon places a stitch on either side of the catheter, if the catheter was placed through the lumpectomy incision.

Add-on Code 19297

After excision of the cancer of the breast and pathology confirmation that the tissue margins surrounding the lumpectomy cavity were free of cancerous cells and that no positive lymph nodes were detected, the remaining breast tissue is examined to ensure adequate tissue for the radiotherapy, afterloading, balloon catheter to be securely positioned. A skin spacing of 5 to 7 mm between the skin and lumpectomy cavity to protect the skin from radiation damage is confirmed. Using either a sterile ruler or imaging guidance, the size and shape of the lumpectomy cavity are evaluated to determine the appropriate technique for the implantation of the catheter. Prior to insertion, the selected balloon catheter is tested by inflating it with a saline solution. The symmetry and integrity of the balloon is assessed and the balloon is deflated.

Next, a separate "stab-like" incision is made near the lumpectomy incision. Through this incision, a trocar is placed to create a separate pathway to the lumpectomy cavity. The catheter is inserted into the lumpectomy cavity via this separate pathway. The balloon catheter is inflated with saline and contrast agent to allow the surrounding tissue to conform to the balloon element of the balloon. The surgeon monitors the amount of fluid during inflation to ensure that the balloon element is appropriately positioned in the lumpectomy cavity for the correct radiation dosimetry, supplied by the radiation oncologist prior to surgery.

The 5- to 7-mm skin spacing between the cavity and skin is reconfirmed to ensure that it has remained intact. The balloon catheter is deflated and withdrawn to allow closure of the lumpectomy site without compromising the integrity of the catheter. After the lumpectomy site is closed, the radiotherapy afterloading balloon catheter is re-advanced and re-inflated to the previously predetermined volume. Placement and integrity of the catheter is verified after inflation with saline and contrast agent. Having verified that the radiotherapy afterloading balloon element of the catheter is secure and appropriately placed, the surgeon places a stitch on either side of the catheter, if the catheter was placed through the lumpectomy incision.

Code 19298

Once the distribution of catheters has been decided, the insertion process can begin. Hollow steel implant needles (or implant tubes with metal style) are used to insert the soft plastic catheters. The physician uses either a freehand or template guided technique. In the freehand technique, the physician determines the proper location and spacing of the brachytherapy catheters by sterile ruler measurements or with the template guide pattern. The entrance and exit sites are marked on the skin with a sterile marking pencil. For the template technique, the physician selects and marks the desired pattern on the template.

The physician selects the correct length needle for each puncture site that corresponds to the tissue distance that must be traversed from the entrance to the exit site. The physician punctures the skin directly with the sterile, hollow, stainless-steel, implant needles or a sharp blade may be needed to nick the skin to facilitate the entrance and exit. The physician advances the needles through the skin and subcutaneous tissue as they are passed from the skin entrance to the exit site (usually tangential to the chest wall). The deep plane of the implant, located at the base of the excision cavity, is implanted first. The physician checks the catheter distribution and spacing through the open excision cavity to ensure full and complete coverage of the tissue. The most superficial plane is optimally 5 mm or more beneath the skin. The physician determines the number of catheters in each plane based upon the width of the region to be treated and the spacing interval between the catheters. The physician inserts the needles with clinical or image guidance or both.

Once the needle or row of needles is in position, the physician replaces them in the tissue with a series of brachytherapy tube catheters. The thin leader-end of the brachytherapy tube catheter is threaded through one end of the hollow needles and it exits at the opposite end, external to the patient. The physician pulls the needle and catheter assembly out as a unit so that the needle is removed and the brachytherapy tube catheter is left in situ. The catheter has a button-shaped or sphere end-piece that prevents it from being pulled through and out with the needle. After the catheter and end-piece are in position near the skin, the physician threads a second fixing button or sphere over the opposite or leader end of the tube of the interstitial catheter so that the apparatus is fixed in the breast tissue on both sides. The physician must check that individual buttons or spheres are placed snuggly, but not tightly, onto the skin to allow for postoperative edema to avoid pressure injury of the skin. The physician inserts each catheter (typically 5 to 10 catheters per plane and 2 to 4 planes per implant) individually.

A series of rows or planes must be created to give a 3-dimensional (3D) volume to the implanted region to achieve a proper treatment distribution that corresponds to the distribution of the disease and avoids important normal tissue structures. The inter-catheter and the inter-plane spacing must be monitored as the insertion proceeds. The brachytherapy tube and button catheters have some degree of rigidity to ensure that the radiation source passes smoothly and safely through the catheter array during treatment. The physician must check that each catheter is patent by passing a nonradioactive dummy cable through the length of the catheter. The physician confirms the position of the catheters within or around the target volume and the lumpectomy cavity by visual inspection, palpation, or by image guidance. The proximal or leader ends of the brachytherapy tube and button interstitial catheters project externally from the skin. The physician cuts them individually to length and the excess length is removed and discarded.

The projecting catheter ends must be prepared to accept the high-dose-rate radiotherapy (HDR) afterloader connection tubing. In addition, the physician removes the internal stiffening-leader stripper device from the individual brachytherapy catheters. (These leaders are used to prevent the brachytherapy catheters from stretching during the pulling maneuver of the catheter insertion process.)

After the catheters are correctly positioned, the dressing is applied. Care must be taken not to

continued on back page

Changes, continued from page 9

bend or kink the catheters, so special padding must be positioned by the physician. The cover sterile dressing is placed over the brachytherapy tube, button catheters, and protection padding. After the brachytherapy devices insertion has been completed, the patient is moved to the recovery area.

Coding Tip

All of the codes in the breast section are unilateral. Any procedures performed on the contralateral (opposite) breast are coded separately or, if the procedure is performed on both breasts.

Summary

Understanding and adopting the newly added introductory guidelines and brachytherapy codes will promote accurate and compliant CPT breast surgery coding. ■

continued from page 14

***single level)* on L4-5 unilaterally, would it be appropriate to append modifier *52, Reduced services*, to code 0062T?**

AMA Comment: If an intradiscal annuloplasty is performed on L4-5 unilaterally it would *not* be appropriate to append modifier 52 because the descriptor for code 0062T includes "unilateral or bilateral" services.

Radiology

Question: Would it be appropriate to report code *76942, Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation*, twice when there is more than one lesion in the breast?

AMA Comment: From a CPT coding perspective, code 76942 should be reported per distinct lesion that requires separate needle placement. Therefore, if several passes are made into two separate lesions in the same organ (ie, two lesions in same breast), then code 76942 would be reported twice. ■

AC29:05-P-024:4/05

cpt Assistant

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The *CPT Assistant* is designed to provide accurate, up-to-date coding information. We continue to make every reasonable effort to ensure the accuracy of the material presented. However, this newsletter does not replace the *CPT* book; it serves only as a guide.

Nucletron

JUN - 8 2005

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Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule (CMS-1478-IFC)

Dear Dr. McClellan:

Nucletron Corporation, located in Columbia, Maryland (Nucletron) is pleased to submit comments regarding the Centers for Medicare and Medicaid Services' (CMS) interim final rule that updates the list of covered procedures provided in an ambulatory surgical center (ASC), which was published in the May 4, 2005 Federal Register.

Nucletron is a medical device company established in 1975 specializing in the development, manufacture, sales, service and support of innovative products used today for radiation therapy cancer treatment. Nucletron has over 110 employees in the United States and is acknowledged as the leading supplier of High Dose Rate (HDR) Afterloading Brachytherapy Systems including High Dose Rate Iridium-192 sources, a wide range of needles and catheters, NRC licensed repair service and source exchange technical service. Nucletron is also a supplier of radiation therapy treatment planning systems, conventional radiation therapy simulators, and Low Dose Rate Brachytherapy Permanent Seeds. Nucletron is a corporate member of AAPM, ASTRO ABS, ACRO, SROA, AAMD and CAB.

CMS has made significant changes to the list of covered services performed in the ASC setting. Nucletron is pleased that CMS added four (4) brachytherapy codes to the list of ASC covered services. We agree with your decision that uterine and breast brachytherapy are appropriate services for the ASC setting. Further, we appreciate the clarification in the interim final rule that payment for brachytherapy procedures does not include the costs of the brachytherapy sources (seeds), which are paid separately under the Medicare Physician Fee Schedule. Our recommendations to CMS are summarized below:

- CMS should assign CPT 19298 to ASC Payment Group 9 at $1,339
- CMS should add CPT 19297 to the list of ASC Covered Services and assign this procedure to ASC Payment Group 9
- CMS should clarify that breast brachytherapy catheters may be paid separately, and in addition to the procedure, under the Medicare Physician Fee Schedule

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Analysis Of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of this Interim Final Rule With Comment Period

I. Additions to the List of ASC Services—CPT 19296 & 19298

Nucletron is appreciative that CMS added two of the three new breast brachytherapy codes to the list of ASC covered services. They are:

- 19296 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy

- 19298 Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance

This issue was brought to the attention of CMS by the Coalition for Advancement in Brachytherapy (CAB) which recommended that both codes be placed in ASC Payment Group 9, however, CMS assigned CPT code 19296 to Payment Group 9, and CPT 19298 to Payment Group 1.

The January 2003 report of the Office of the Inspector General (OIG) entitled "Payments for Procedures in Outpatient Departments and Ambulatory Surgical Centers" concluded that there should be a greater parity of payment for services performed in an outpatient setting and those performed in ASCs. Under the Hospital Outpatient Prospective Payment System both codes are assigned to APC 1524 with a payment of $3,250 because they are similar both clinically and with respect to resource utilization. Payment of $333.00 for CPT 19298 does not cover the facility costs of this procedure and creates a large disparity of payment for HDR brachytherapy performed in the ASC setting from services provided in the hospital outpatient setting. CMS should reassign CPT 19298 to ASC Payment Group 9 at $1,339. The proposed payment of $333.00 will discourage utilization of HDR breast brachytherapy in the ASC setting and will not provide for appropriate reimbursement of the cost to provide this care.

Partial breast irradiation with HDR brachytherapy requires the surgical insertion of catheter(s) into the breast. CPT 19296 involves a single balloon catheter inserted into the lumpectomy cavity and inflated prior to radiation therapy. CPT 19298 involves interstitial placement of 12 to 36 catheters surrounding the lumpectomy cavity prior to radiation therapy. CPT 19296 and 19298 are procedures that are similar clinically and require similar resource consumption. **CPT 19298 should be also be assigned to Payment Group 9 because the procedure often involves more facility time and is more intense clinical procedure than CPT 19296.** Technical costs include the facility

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time, technical staff time, anesthesia and general supplies. Both procedures can be safely performed in the ASC.

Nucletron recommends that CPT 19298 should be assigned to ASC Payment Group 9

II. Additions to the List of ASC Services—CPT 19297

In correspondence dated January 14, 2005, CAB recommended that CPT code 19297 be added to the list of ASC covered services and assigned to Payment Group 9 as this procedure is similar clinically to CPT 55859 prostate brachytherapy needle placement.

- 19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy)

CMS did not include CPT 19297 on the updated list of ASC services and stated that this was an "add-on" procedure that is included in another procedure and not performed on its own. This procedure is exactly the same as CPT 19296 except that it is performed on the same day as the partial mastectomy, and 19296 is performed on a later date after the partial mastectomy. Although the CPT description of 19297 lists this procedure as an "add on" procedure, this procedure is unique and distinct from the partial mastectomy primary procedure. The primary procedures are approved ASC procedures, and 19297 can be safely performed in the ASC as a secondary procedure to the primary surgery, just as in the hospital outpatient department. Costs are similar as the resources for this procedure, including facility time, staff, anesthesia and general supplies are equivalent to 19296.

Nucletron recommends that CPT 19297 should be added to the list of ASC covered services and assigned to ASC Payment Group 9. This "add-on" procedure is separate and distinct from the partial mastectomy and the facility costs associated with CPT 19297 are significant.

III. Clarification of Separate Payment for Brachytherapy Catheters—A4649

Nucletron understands that brachytherapy payment policy is complex. We appreciate the clarification in the interim final rule that payment for brachytherapy procedures does not include the costs of the brachytherapy sources (seeds).

Nucletron recommends that CMS make clear that brachytherapy catheter(s) are also paid separately as are other brachytherapy devices (Q3001) utilized in brachytherapy procedures. Catheters should be purchased by the surgeon and billed by the surgeon under Medicare Part B fee schedule using A4649. The breast brachytherapy catheter(s) range in cost from $2,500 to $3,500 per patient, and are clearly not covered supplies under the ASC fee schedule. The catheters would be purchased by the physician and

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billed separately under the Medicare Physician Fee Schedule in addition to the procedure following the same payment methodology as brachytherapy sources.

Nucletron requests that CMS clarify in the ASC rule that breast brachytherapy catheters may be coded as A4649 *Surgical supply, miscellaneous* and be billed by the surgeon and paid separately under the Medicare Part B Physician Fee Schedule.

High Dose Rate Brachytherapy offers important cancer therapies to Medicare patients. Appropriate payment for brachytherapy procedures and sources will ensure that Medicare beneficiaries have full access to high quality cancer treatment in an ambulatory surgical center.

Nucletron appreciates the opportunity to provide comments for review and welcomes the opportunity to meet with officials to discuss future payment via conference call. Please contact Kathy Francisco, at The Pinnacle Health Group, 215-369-9290 to discuss this issue in further detail or schedule a meeting and/or conference call regarding this issue.

Sincerely,

Raymond Horn
Director of Clinical Affairs
Nucletron Corporation

7

Lifeline Inc.

JUN 1 3 2005

June 6, 2005

Department of Health and Human Services
Attention CMS-1478-IFC
PO Box 8017
Baltimore, Md. 21244-8017

We are commenting on the removal of CPT codes 35475 and 35476 from the Final Rule of Medicare approved ambulatory surgical center (ASC) procedures. CMS proposed including these codes in a Proposed Final Rule and then withdrew them in its recent Final Rule. We believe these two angioplasty procedures should be permitted in an ASC setting. The reversal was not appropriate given the ample clinical evidence available that demonstrates their safety in an outpatient setting.

It appears that CMS removed CPT codes 35475 and 35476 from the list of Medicare approved additions to the ASC procedures because of one comment received during the Proposed Rule comment period. That comment was found on page 43 of the Final Rule.

> "Comment: We received many comments in support of the proposed additions to the ASC list. However, we received one comment that opposed the additions of CPT codes 37205, 37206, **35475**, and **35476**. The commenter stated that these procedures were not appropriate for the ASC setting and would allow for potential substandard care.
> Response: Our medical staff's reconsideration of these procedures led to our decision not to add them to the ASC list. The procedures involve major vessels and therefore do not meet our criteria for inclusion on the ASC list."

The specific CPT code description for those two codes is:

- 35475 - transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
- 35476 - transluminal balloon angioplasty, percutaneous; venous

These codes are safe and appropriate for the ASC setting.

RMS Lifeline is a practice management company specializing in the management of dialysis vascular access centers for physician practices. We currently manage the operations of 16 centers for different physician practices around the country. These centers are not licensed as ASC's, but are office based surgical centers. The centers are generally constructed to meet ASC specifications in the states in which they operate, even though they do not operate as that place of service. These centers work exclusively with dialysis patients and their vascular access for hemodialysis.

Three Hawthorn Parkway, Suite 410 Vernon Hills, IL 60061 phone 847-388-2001 fax 847-388-2020

Vascular access is one of the greatest sources of complications and cost for dialysis patients. These centers routinely provide thrombectomy/declot procedures to remove blood clots from the vascular access, angiography to determine blood flow, angioplasty to improve blood flow, and a variety of permanent hemodialysis catheter procedures for dialysis patients. Angioplasty data from our managed centers from October 1, 2002 to May 5, 2005 shows the following:

- 16,319 patients had procedures performed, including 14,961 venous angioplasties and 3,078 arterial angioplasties. [The reason that the number of procedures performed exceed the number of patients is due to the fact that some patients require multiple procedures.]
- 15,982 patient encounters (97.9%) were successful as defined by the Society of Interventional Radiology standard of having less than 30% stenosis remaining post procedure. 180 (1.1%) procedures were deemed unsuccessful, and 157 (.9%) were aborted.

The complications are detailed below:

Complication Type	
Hematoma Grade I	254
Hematoma Grade II	27
Hematoma Grade III	7
Oxygen Saturation < 90%	5
Apnea, Temporary	3
Low BP or Pulse	4
Reaction to Medication	23
Bleeding	4
Foreign Body Failure	12
Foreign Body Retrieved	2
Death	4
Other	8

In total there were 353 complications (2.2 % of the procedures), and of those 25 were major complications and 328 were minor.

According to the reporting standards of the Society for Interventional Radiology, all complications, including pulmonary and cardiac events that occur within 30 days following the procedure are considered procedure related. Minor complications are those that require either no therapy or only nominal therapy and resolved without any adverse consequence. Major complications are defined as those that require an increase in the level of care, or result in hospitalization, permanent adverse sequelae or death. The threshold for complications using this classification scheme has been defined as 5%. A total complication rate of 2.2 % is well below the established threshold. Of these, 2% were minor complications, meaning that they resulted in no significant change in medical management and resolved without sequelae. Only 0.2% of the complications were major. The 4 deaths that occurred were not as a direct result of the procedure performed, but did fall within the complication definition.

This large compilation of data clearly demonstrates that both venous and arterial angioplasty can be safely and effectively performed in the outpatient setting. One-hundred percent of the patients in this series were queried using the Ware Patient Satisfaction survey tool. The response rate for this survey was 40%. Patient satisfaction was very high. 88% of the respondents rated their experience at these centers as either very good or excellent.

The data shown here comes from office based surgical centers, which is highly comparable to an ASC setting in many ways, but different in its legal structure. It is important to approve these procedures in an ASC setting too. An ASC facilitates more widespread availability of these procedures for ESRD patients. The extension of practice, office based surgical center works well for large physician groups with large patient populations. The ASC allows smaller physician practices to provide smaller patient populations with the same service. Including 35475 and 35476 as approved procedures in the ASC setting will expand the number of patients who can have dialysis vascular access complications treated in an ASC versus the hospital.

We ask that CMS and its medical staff review this data and reconsider its decision. Yes, these procedures do involve major vessels, but we believe we have provided compelling data that shows angioplasty can be safely and effectively performed in an ASC setting. Several other procedures are already approved on the ASC list and involve major vessels – 36558, 36581, 36589, 36819, 36820, 36821, 36825, 36830, and 36870 among others in the 36000 and 37000 series approved codes. We request that CPT codes 35475 and 35476 be added to the current list of Medicare approved ASC procedures in Payment Group 9. Thank you for your consideration.

Sincerely Yours,

Gerald A. Beathard, M.D.
Vice President, Provider Services

Richard Nee
Vice President and General Manager

Literature

Below is listed some of the publications that have appeared in peer reviewed journals supporting the safety of these procedures:

1. Beathard GA: Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. Kidney Int 42:1390-1397, 1992
2. Beathard GA: Percutaneous angioplasty for the treatment of venous stenosis: A nephrologist's view. Semin Dial 8:166-170, 1995
3. Beathard GA, Settle SM, Shields MW: Salvage of the nonfunctioning arteriovenous fistula. Am J Kidney Dis 33:910-916, 1999
4. Khan FA, Vesely TM. Arterial problems associated with dysfunctional hemodialysis grafts: evaluation of patients at high risk for arterial disease. J Vasc Interv Radiol 13:1109-1114, 2002
5. Vesely TM. Endovascular intervention for the failing vascular access. Adv Ren Replace Ther 9:99-108, 2002
6. Beathard GA: Angioplasty for arteriovenous grafts and fistulae. Semin Neph 22:202-210, 2002
7. Beathard GA, Arnold P, Jackson J, Litchfield T: Aggressive treatment of early fistula failure. Kidney Int 64:1487-1494, 2003
8. Beathard GA: Management of complications of endovascular dialysis access procedures. Semin Dial 16:309-313, 2003
9. Asif A, Merrill D, Briones P, Roth D, Beathard GA. Hemodialysis vascular access: percutaneous interventions by nephrologists. Semin Dial. 17:528-534, 2004
10. Beathard GA, Litchfield T, Physician Operators Forum of RMS Lifeline, Inc: Effectiveness and Safety of Dialysis Vascular Access Procedures Performed by Interventional Nephrologists. Kidney Int 66:1622-1632, 2004
11. Surowiec SM, Fegley AJ, Tanski WJ, Sivamurthy N, Illig KA, Lee DE, Waldman DL, Green RM, Davies MG. Endovascular management of central venous stenoses in the hemodialysis patient: results of percutaneous therapy. Vasc Endovascular Surg 38:349-354, 2004
12. Sprouse LR 2nd, Lesar CJ, Meier GH 3rd, Parent FN, Demasi RJ, Gayle RG, Marcinzyck MJ, Glickman MH, Shah RM, McEnroe CS, Fogle MA, Stokes GK, Colonna JO. Percutaneous treatment of symptomatic central venous stenosis. J Vasc Surg 39:578-582, 2004

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Michael N. Bucci, M.D., F.A.C.S.
Aaron C. MacDonald, M.D., F.A.C.S.
Christie B. Mina, M.D.

June 6, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
~~Attention: CMS-0011-P~~
P.O. Box 8014
Baltimore, MD 21244-8014

RE: File code CMS-1478-IFC

Dear Administrator McClellan:

I appreciate the chance to comment on proposed changes to the ACS approved procedures. As a relatively busy neurosurgeon in private practice in a small to moderate community setting, it would be extremely valuable to include the following codes for spinal surgery to the approved ASC list:

63030 – Laminotomy, with decompression of nerve roots and/or excision of herniated intervertebral disk; one interspace, lumbar.

63035 – Laminotomy, with decompression of nerve roots and/or excision of herniated intervertebral disk; each additional interspace, lumbar.

63042 – Laminotomy, with decompression of nerve roots(s), and/or excision of herniated intervertebral disc, re-exploration, single interspace, lumbar.

63047 – Laminectomy, facetectomy and foraminotomy, (eg, spinal or lateral recess stenosis), single vertebral segment, lumbar.

63048 – Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis), single vertebral segment; each additional segment, cervical, thoracic, or lumbar.

We have been performing outpatient procedures on these codes in most of our patients over the past four to eight years with very little morbidity related to the procedure being performed in the outpatient surgical setting.

Surgical technology advanced to facilitate minimally invasive techniques for performing these procedures limiting the stress related to the surgical operation facilitating early mobilization and recovery. It has been our experience that most patients request discharge home following their surgery, however, due to limitations based on these codes and their lack of presence on the ACS list, they are required to spend the night in the inpatient hospital setting.

I believe adding these codes to the approved ACS list will increase access to quality care and reduce costs.

Sincerely,

Aaron C. MacDonald, M.D., F.A.C.S.

ACM/pwc

JUN 17 2005

VNUS®
MEDICAL TECHNOLOGIES, INC.

June 16, 2005

VIA: COURIER

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule with Comment Period. File Code CMS-1478-IFC, Issue Identifier: Additions and ASC Group Assignment of Procedures that were not Proposed for Addition in the November 26, 2004, Rule.

Dear Administrator McClellan:

On behalf of VNUS Medical Technologies, Inc. (VNUS), we appreciate the opportunity to comment on the interim final rule published by the Centers for Medicare & Medicaid Services (CMS) on May 4, 2005, which provides an update of the ambulatory surgical center list of covered procedures.[1] VNUS is a small medical device company that manufactures state-of-the-art medical systems that employ radiofrequency energy for the treatment of vascular diseases. Our products include the VNUS Closure Procedure (Endovenous Radiofrequency Ablation (RFA) for Superficial Venous Reflux), which offers a highly effective and less invasive treatment for symptomatic venous insufficiency.

This comment letter concerns CMS's assignment of CPT 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein) and add-on code CPT 36476 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites) to ASC payment group 3. CMS based this assignment on clinical similarity (in terms of the clinical treatment objective) of these codes with procedures currently assigned to group 3. However, we

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[1] See Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule, 70 Fed. Reg. 23690 (May 4, 2005).

contend that this assignment is an error that CMS should correct in the final ASC rule by not adding these codes to the ASC list. CMS correctly states in the background section of the IFR that there is no clinical consistency among the procedures in a payment group and that group assignment is based solely on estimated facility costs. Therefore, the assignment of 36475 and 36476 to group 3 based on clinical similarity without consideration of facility costs is at odds with this stated methodology for ASC payment group assignment.

Because ASC payment group assignment is supposed to be based on facility costs and because of the current lack of ASC facility cost data for 36475, we recommend that CPT 36475 and 36476 not be added to the ASC list at this time. This recommendation is supported by Robert Zwolak, M.D., the originator of the comment on the proposed rule that led to the addition of these codes to the ASC list. We anticipate that Dr. Zwolak will also submit a comment letter to CMS recommending that these codes not be added to the ASC list at this time. CMS can add these codes to the ASC list in the future when facility cost data is available for CPT 36475 and CPT 36476.

I. PROPOSED ADDITION OF CPT 36475 AND CPT 36476 TO THE ASC LIST AND ASSIGNMENT OF THESE CODES TO PAYMENT GROUP 3

In response to a comment on the proposed rule, CMS is now proposing to add CPT 36475 and CPT 36476 to the ASC list. We agree with CMS that these codes are clinically appropriate for the ASC setting, but we disagree with the assignment of these codes to payment group 3. CMS's reason for the assignment of these codes to payment group 3 is explained in the following statement from the IFR: "We will assign the codes to payment group 3 consistent with other procedures with similar clinical indications." This approach of basing an ASC payment group assignment on similar clinical indications to other procedures contradicts CMS's stated methodology for ASC payment group assignments.

CMS explicitly states in the IFR in section I E (Current ASC Payment Rates) that: "There is no clinical consistency among the procedures in a payment group. Rather, assignment to a payment group is based solely on an estimate of facility costs associated with performing the procedures."[2] Furthermore, CMS states in the IFR: "The payment group for each addition to the ASC list in this interim final rule is based on the payment group to which procedures currently on the list, which our medical advisors judged to be similar in time and resource inputs, are assigned.[3] Therefore, the assignment of CPT 36475 and CPT 36476 to an ASC payment group should be based on the facility costs of

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2 See 70 Fed. Reg. 23690, 23692.

3 Id.

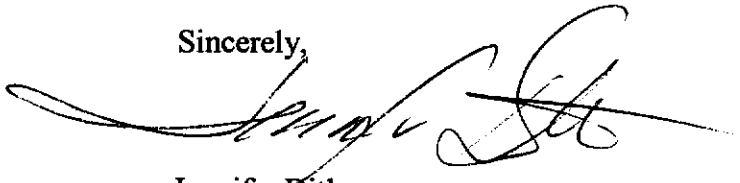
performing the procedure in an ASC, and placed in a group with procedures that have similar time and resource inputs.

II. ASC FACILITY COSTS FOR CPT 36475 AND 36476 GREATLY EXCEED THE GROUP 3 PAYMENT AMOUNT

Appendix A provides a detailed list of the estimated costs associated with the VNUS Closure Procedure in the physician office setting and the hospital outpatient setting. Based on these estimates, the estimated ASC facility costs would be expected to range from **$2000 (office) to $4800 (hospital)**, which greatly exceeds the $510 group 3 payment. By comparison, the national average nonfacility physician fee schedule payment for CPT 36475 = $2216.25. When the facility physician fee schedule payment of $364.57 is subtracted, the additional practice expenses associated with performing this procedure in the office = $1851.68. This value was created by the PEAC, agreed upon by the RUC, and ratified by CMS. Also by comparison, for the hospital outpatient setting, CPT 36475 is assigned to APC 92, which pays a national average of $1538.27. Therefore, the ASC group 3 payment of $510 is only 30% of the Medicare payment for the practice expenses associated with doing the procedure in the physician's office, and it is only 33% of the APC payment in the hospital outpatient setting. Payment for 36475 at the ASC group 3 level is severely insufficient for endovenous radiofrequency therapy and does not correlate with either the estimated range of ASC facility costs or the current Medicare reimbursement in either the physician office setting or the hospital outpatient setting. If 36475 is relegated to ASC group 3, the result will be a site of service bias based on differential payment for either the physician office or the hospital outpatient setting, regardless of which setting would best serve the individual patient.

VNUS appreciates the opportunity to comment on the IFR, and strongly believes that it would be most appropriate to not add 36475 and 36476 to the ASC list at this time. We are eager to provide CMS with any additional information that would enable the agency to properly assign endovenous radiofrequency therapy to an appropriate ASC payment group. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me at (408) 473-1128.

Sincerely,



Jennifer Ditlow
Reimbursement Director
VNUS Medical Technologies

Resources needed for radiofrequency ablation of venous reflux

Labor	Office Cost	Hospital Cost
1 Scrub Nurse (1.5 hr: $50/hr)	$75	$75
1 Circulating nurses (1.5 hr: $50/hr)	$75	$75
1 Vascular Ultrasound Technologist (1 hr: $50/hr)	$50	$50
Total Labor Costs	$200	$200
O.R. or Procedure Room Time		
1.5 hours @ $500 per unit (1 hour/unit – office; 15 mins./unit – hospital)	$750	$3,000
Supplies		
Patient Preparation		
Betadine, 4 oz bottle	$8.98	$8.98
Scrub brush – for betadine application	$0.91	$0.91
Heating pad	$15.00	$15.00
Sterile drapes Split Sheet	$6.50	$6.50
Half Sheet	$0.41	$0.41
Back Table Cover	$2.42	$2.42
Sterile gloves	$3.14	$3.14
Sterile gowns	$19.76	$19.76
Masks	$0.80	$0.80
Skin marker for pre-operative vein mapping	$1.50	$1.50
Sterile cover for ultrasound transducer	$10.83	$10.83
Non-sterile ultrasound gel – bottle	$2.50	$2.50
Sterile ultrasound gel packets	$6.00	$6.00
Sedation:		
p.o. Valium 10 mg tabs	$0.06	N/A
I.V. Versed 5 mg per cc	$19.03	$19.03
General anesthesia	N/A	$450
Vein access		
27g hypodermic needle	$0.05	$0.05
1% Lidocaine without epinephrine 50ml vial	$6.65	$6.65
Micro-puncture kit with 21g needle, 0.018" & 0.035" guidewires	$45.00	$45.00
6F or 8F introducer sheath	$13.00	$13.00
Scalpel w/ #11 blade	$0.75	$0.75
Suture	$3.39	$3.39
Nitroglycerine paste	$23.00	$23.00
Tumescent Fluid Infiltration:		
20 or 22 g, 3.5" spinal needle	$2.40	$2.40
Quantity of three 20 or 30cc syringes	$1.65	$1.65
Sodium bicarbonate 50ml 8.4%	$1.08	$1.08

1% Lidocaine with epinephrine 50 ml vial	**$15.64**	**$15.64**
Procedure		
RF ablation catheter (Closure catheter)	**$725.00**	**$725.00**
IV administration sets	**$2.02**	**$2.02**
Sterile IV extension set	**$0.84**	**$0.84**
Sterile normal saline, 250ml	**$6.59**	**$6.59**
Heparin dosage 10,000 u/L	**$3.68**	**$3.68**
Sterile bowls 250cc	**$8.30**	**$8.30**
500 cc	**$5.25**	**$5.25**
Sterile gauze 4x4s	**$1.72**	**$1.72**
Sterile Esmark bandage	**$4.50**	**$4.50**
Sterile towels	**$6.60**	**$6.60**
Syringes 10 ml	**$0.23**	**$0.23**
Steristrips	**$1.84**	**$1.84**
Y-connector w/ back-check valve	**$6.50**	**$6.50**
0.025" PTFE-coated guidewire	**$20.00**	**$20.00**
Post-operative dressings - 5x7 ABD pads	**$0.47**	**$0.47**
Kerlix	**$4.90**	**$4.90**
Gauze, non-sterile	**$1.27**	**$1.27**
Compression stockings/hose 15-20 mmHg or 20-30 mmHg	**$78.00**	**$78.00**
Total supplies cost per case including catheter	**$1,088**	**$1,538**
Post-Anesthesia Recovery		
One hour @ $150/hour	**N/A**	**$150**
Overhead		
(Not specified, please use standard designation if desired)	---	
Total Costs Associated with RFA Procedure	**$2,038**	**$4,888**
Equipment		
VNUS RF Generator	**$25,000**	**$25,000**
VNUS Footswitch	**$275**	**$275**
Duplex ultrasound system	**$40,000 for ports**	**$40,000 for ports**
Tilt Table	**$6,900**	**$6,900**
Autoclave unit	**$2950**	**$2950**
Pressure bag for heparinized saline drip	**$16.75**	**$16.75**
IV pole	**$23.77**	**$23.77**
Hemostats – curved mosquito	**$17.44**	**$17.44**
Total equipment cost (overall-not depreciated)	**$75,183**	**$75,183**

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JUN 2 3 2005

American College of Radiation Oncology
5272 River Road • Suite 630 • Bethesda, MD 20816
(301) 718-6515 • FAX (301) 656-0989 • EMAIL acro@paimgmt.cc

June 15, 2005

Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule (CMS-1478-IFC)

Dear Dr. McClellan:

The American College of Radiation Oncology (ACRO) represents approximately 1,700 radiation oncology physicians and would like to provide comments regarding the Centers for Medicare and Medicaid Services' (CMS) interim final rule that updates the list of covered procedures provided in an ambulatory surgical center (ASC), which was published in the May 4, 2005 Federal Register relating to brachytherapy codes 19296, 19297, 19298, 57155 and 58346. ACRO is the only organization that exclusively, and uniquely, represents radiation oncologists in the socioeconomic and political sphere without influence from any other specialty.

Brachytherapy is unique in that it requires significant resources, time and expertise. It is sometimes better for patients (and reduces morbidity and cost) if done in conjunction with other surgical procedures. However, even when done in conjunction with other procedures, it requires the same amount of extra resources, time and expertise as when done alone.

We appreciate CMS making changes to the list of covered services performed in the ASC setting. ACRO is pleased that CMS has added CPT codes 19296, 19297, 19298 and 57155 to the list of ASC covered services. We are glad that CMS has clarified in the interim final rule that payment for brachytherapy procedures does not include the costs of the brachytherapy sources (seeds), which are paid separately under the Medicare Physician Fee Schedule. ACRO would recommend that CMS consider the following recommendations:

- CMS should assign CPT 19298 to ASC Payment Group 9 at $1,339
- CMS should add CPT 19297 to the list of ASC Covered Services and assign this procedure to ASC Payment Group 9
- CMS should clarify that breast brachytherapy catheters may be paid separately, and in addition to the procedure, under the Medicare Physician Fee Schedule
- CMS should assign CPT 57155 to ASC Payment Group 9 at $1339.00
- CMS should assign CPT 58346 to ASC Payment Group 9 at $1339.00

Analysis Of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of this Interim Final Rule With Comment Period

I. Additions to the List of ASC Services—CPT 19296 & 19298

ACRO is appreciative that CMS added two of the three new breast brachytherapy codes to the list of ASC covered services. They are:

- 19296 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy

- 19298 Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance

Both procedures are similar in that placement of devices is required into the breast for radiation. A similar amount of additional time, supplies and additional resources would be required for these procedures. CMS has assigned CPT code 19296 to Payment Group 9, and CPT 19298 to Payment Group 1. ACRO would recommend that both CPT code 19296 and 19298 be assigned to Payment Group 9.

Under the Hospital Outpatient Prospective Payment System both codes are assigned to APC 1524 with a payment of $3,250 and it is recognized that they are similar both clinically and with respect to resource utilization. The January 2003 report of the Office of the Inspector General (OIG) entitled "Payments for Procedures in Outpatient Departments and Ambulatory Surgical Centers" concluded that there should be a greater parity of payment for services performed in an outpatient setting and those performed in ASCs. We feel that these procedures are recognized to be similar in terms of resource utilization under the Hospital Outpatient Prospective Payment System, and that there should be parity for services performed in an outpatient setting and those performed in

ASCs. If CPT 19298 is paid at Group 1 rates (of $333.00), then this will not be adequate to cover the facility costs of this procedure and creates a large disparity of payment for HDR brachytherapy performed in the ASC setting from services provided in the hospital outpatient setting. CMS should reassign CPT 19298 to ASC Payment Group 9 at $1,339.

Technical costs include the facility time, technical staff time, anesthesia and general supplies. CPT 19298 should be also be assigned to Payment Group 9 because the procedure takes just as long and is involved with an intense time element (similar or more than CPT 19296). Both procedures can be safely performed in the ASC.

ACRO recommends that CPT 19298 should be assigned to ASC Payment Group 9.

II. Additions to the List of ASC Services—CPT 19297

CPT Code 19297 is:

- 19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy

CMS did not include CPT 19297 on the updated list of ASC services and stated that this was an "add-on" procedure that is included in another procedure and not performed on its own. We are confused since this procedure is exactly the same as CPT 19296 except that it is performed on the same day as the partial mastectomy. Patients would probably prefer to have this invasive procedure performed on the same day as their surgery, so as to avoid them having to come in on another day for this catheter placement. Excluding CPT 19297 would discourage placement of the radiotherapy afterloading balloon catheter at the time of the partial mastectomy, and will not provide for appropriate reimbursement of the cost to provide this care. CPT 19297 involves the insertion of balloon catheter into the lumpectomy cavity. After catheter placement, the balloon is inflated and the breast is treated with the Iridium-192 high intensity (high dose rate or HDR brachytherapy) afterloading device. Although the CPT description of 19297 lists this procedure as an "add on" procedure, this procedure is unique and distinct from the partial mastectomy primary procedure. (See attachment 2, April 2005 AMA "CPT Assistant" for more clinical detail). The primary procedures are approved ASC procedures, and 19297 can be safely performed in the ASC as a secondary procedure to the primary surgery, just as in the hospital outpatient department. Costs are similar as the resources for this procedure, including facility time, staff, anesthesia and general supplies are equivalent to 19296.

III. Clarification of Separate Payment for Brachytherapy Catheters—A4649

ACRO understands that brachytherapy payment policy is complex. We appreciate the clarification in the interim final rule that payment for brachytherapy procedures does not include the costs of the brachytherapy sources (seeds).

ACRO recommends that CMS make clear that brachytherapy catheter(s) are also paid separately as are other supplies utilized in brachytherapy procedures. Catheters should be purchased by the surgeon and billed by the surgeon using A4649. The breast brachytherapy catheter(s) range in cost from $2,500 to $3,500 per patient, and are clearly not covered supplies under the ASC fee schedule. The catheters would be purchased by the physician and billed separately under the Medicare Physician Fee Schedule in addition to the procedure following the same payment methodology as brachytherapy sources.

ACRO requests that CMS clarify in the ASC rule that breast brachytherapy catheters may be coded as A4649 *Surgical supply, miscellaneous* and be billed by the surgeon and paid separately under the Medicare Part B Physician Fee Schedule.

IV. Additions to the List of ASC Services—CPT 57155 and 58346

ACRO is appreciative that CMS has added a gynecologic procedures CPT 57155 and 58346 to ASC covered services

- 57155 Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy.
- 58346 Insertion of Heyman capsules for clinical brachytherapy.

This procedure involves insertion of tandem and ovoids under direct visualization of the uterine/cervical cancer. ACRO would recommend that both CPT code 57155 be assigned to Payment Group 9.

ACRO recommends that CPT 57155 and 58346 should be assigned to ASC Payment Group 9.

Brachytherapy—the specific placement of radiation within diseased tissue using catheters or seeds—permits targeted radiation to the cancer area while minimizing exposure to surrounding radiosensitive normal tissues. Especially for breast cancers, this often allows patients the ability to have the radiation delivered faster than can be delivered with conventional radiation treatments. Sufficient reimbursement to cover costs associated

with placement of these brachytherapy devices is crucial to Medicare patients having full access to these treatments in a time-saving manner in ambulatory surgical centers.

ACRO appreciates your consideration of our recommendations and welcomes the opportunity to meet with you to further discuss our suggestions. If you require additional information or have questions, please contact Norman Wallis, PhD, Executive Secretary at Tel: 301-718-6539 or Fax: 301-656-0989.

Sincerely,

D. Jeffrey Demanes, M.D.
President

Michael Kuettel, M.D., Ph.D.
Chair, Economics Committee

W. L. GORE & ASSOCIATES, INC.
1505 NORTH FOURTH STREET • P.O. BOX 2400 • FLAGSTAFF, ARIZONA 86003-2400
PHONE: 928/526-3030 • FAX: 928/526-3815

JUN 27 2005

June 24, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Ref: CMS-1478-IFC Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule

We appreciate the opportunity to submit comments on the ASC Interim Final Rule as published in the Federal Register, Vol. 70, No. 85 on May 4, 2005.

Section II. "ANALYSIS OF AND RESPONSES TO PUBLIC COMMENTS RECEIVED ON THE NOVEMBER 26, 2004 PROPOSED RULE AND PROVISIONS OF THIS INTERIM FINAL RULE WITH COMMENT PERIOD"

We *support* the CMS medical staff's reconsideration of CPT® codes 37205, 37206, 35475, and 35476 which will not be included in the List of Covered ASC procedures. In the current ASC setting, limited clinical staffing and facilities do not support the addition of these procedures. As CMS will be developing a new payment system and reviewing the criteria for determining ASC procedures, these CPT® codes will more appropriately be included in this more comprehensive analysis.

Thank you for your consideration of these comments.

Sincerely,

Antoinette L. Sheen

Antoinette L. Sheen, MBA (Ext. 42420)
Coverage, Coding & Reimbursement
W. L. Gore & Associates Inc.
1505 N. Fourth St.
Flagstaff, AZ 86004

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ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Henry Alder
Director
Reimbursement & Healthcare Economics
4545 Creek Road, ML 90
Cincinnati, Ohio 45242
(513) 337-3201

June 23, 2005

The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
Box 8017
Baltimore, MD 21244-8017

JUN 27 2005

RE: CMS-1478-IFC: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures.

On behalf of Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company, we wish to submit an additional comment as a follow-up to our meeting with Ms Joan Sanow on May 24, 2005 regarding the Proposed Addition of CPT 46947 – Hemorrhoidopexy by stapling to the ASC list (page 23709) to a higher payment group.

We recommend reassigning CPT code 46947 from payment group 3 to payment group 7, 8 or 9 in the 2005 Update of Ambulatory Surgical Center List of Covered Procedures.

From a health policy perspective, we believe we have sound arguments for increasing the payment for CPT code 46947. The change to a higher paying payment group should be made as soon as possible. Waiting for the next major update (in 2007) is inappropriate. Further, not making the change now will limit access to the procedure in the ASC setting and create an uneven playing field with hospitals.

At our meeting with Ms Sanow we were informed that CMS resources would not permit reassigning payment groups for procedures on the 2005 Update of ASC List of Covered Procedures, because resources are being directed to the 2007 update. As described in the attachments, CPT code 46947 requires the use of a significant surgical supply – Hemorrhoidal Circular Stapler – that costs $389, or 76% of the proposed ASC payment.

Thank you for your consideration of our comments and recommendations. We look forward to continuing to work with you and your staff in resolving these complex issues.

Sincerely,

Henry Alder
Director – Reimbursement & Healthcare Economics

Enclosure – Presentation Slides – Joan Sanow Meeting – May 24, 2005

cc. Kathy Buto
Greg White
Joan Sanow
Bob Cereghino

Ethicon Endo-Surgery, Inc.
Meeting with
Ms. Joan Sanow
Center for Medicare & Medicaid Services

May 24, 2005

SITUATION REVIEW

- ***Hemorrhoidopexy by stapling (or PPH) is added to the 2005 Update of Ambulatory Surgical Center List of Covered Procedures***
  - PPH (CPT 46947) – Payment Group 3
- ***CMS medical staff considers PPH similar to complexity to other hemorrhoidectomy procedures (such as CPT code 46257, hemorrhoidectomy, internal and external, with fissurectomy)***
  - CPT 46257 – Payment Group 3
- ***Only PPH requires the use of a significant surgical supply – Hemorrhoidal Circular Stapler – which costs $389.***
- ***PPH device costs are 76% of proposed ASC payment***

*Source: Federal Register, May 4, 2005.

FACTS PROOF

ASC Facility Payment for Hemorrhoidectomy Treatments

	Int & Ext Hemorrhoid w/Fissure	Stapled Hemorrhoidopexy (PPH)
CPT Code	46257	46947
ASC Group	3	3 (Proposed)
2005 ASC Payment*	$510	$510 (Proposed)
Device Cost	-0-	$389
Equipment & Supply Cost**	$184	$572

Source: * ASC Group and 2005 Payment (Effective July 1, 2005) - Federal Register, May 4, 2005;
** Equipment & Supply Cost – Deloitte Consulting Medical Supply Expense Survey, April 2004.
(Note – Procedure labor and overhead are NOT included in equipment & supply cost.)

Recommendation

- **We respectfully recommend reassigning Hemorrhoidopexy by Stapling (PPH) – CPT code 46947 – from Payment Group 3 to Payment Group 7, 8 or 9.**

PPH03 Pricing

- PPH is available as drop ship only; during this time all drop ship fees will be waived.
- Preceptee certification must be received prior to product ordering.

Product Code	Product Description	Suggested Hospital Price	Instruments Per Sales Unit
PPH03	Hemorrhoidal Circular Stapler, Suture Threader, Circular Anal Dilator, and Purse-String Anoscope	$1167 ($389 each)	3

Itemized List of Equipment and Supply Costs Incurred by Hospital to Provide Ferguson Hemorrhoidectomy (CPT 46255) and Stapled Hemmoroidopexy (CPT 46947)

	Ferguson Quantity	PPH Quantity	Each Price	Ferguson Supply Cost		Stapled Hemorrhoidopexy Supply Cost
PREOP ITEMS						
Anesthetic, rectal IM, local (20 cc Marcaine/Lidocaine/sod bicarb)	20	20	$1.75	$35.00		$35.00
Hospital Johnny (Patient Gown)	1	1	$5.20	$5.20	Reusable	$5.20
Intravenous Line, Stopcock	1	1	$1.30	$1.30		$1.30
Intravenous Line, Tubing	1	1	$2.40	$2.40		$2.40
Intravenous Line, Cath Insyte Autoguard 18	1	1	$1.68	$1.68		$1.68
Intravenous Fluid, Lactated Ringers, 1000cc	1	1	$0.84	$0.84		$0.84
Sterile gauze, 4x4, 16 ea.	2	2	$0.79	$1.58		$1.58
Socks, non-slip, pairs	1	1	$2.43	$2.43		$2.43
Tourniquet, disposable	1	1	$0.10	$0.10		$0.10
UPT (urine pregnancy test)	1	1	$2.50	$2.50	Estimate	$2.50
Tegaderm(small)	1	1	$1.97	$1.97		$1.97
Gloves	1	1	$2.94	$2.94		$2.94
2% Lidocaine and epidural kit (spinal block, not for every patient)	1	1	$18.33	$18.33		$18.33
INTRAOP ITEMS						
Anesthetic for Sedation (Propofol and Versed and Fentanyl)	pending pt (mg/kg)	pending pt (mg/kg)	$6.00	$6.00		$6.00
Anoscope series	1	1	$1.29	$1.29		$1.29
Basin set	1	1	$12.95	$12.95		$12.95
Betadine, oz	30	30	$0.10	$3.00		$3.00
Cannula, oxygen	1	1	$1.31	$1.31		$1.31
Drape, patient	1	1	$1.21	$1.21		$1.21
Drape, sterile, mayo stand	1	1	$0.91	$0.91		$0.91
Gloves, non-sterile	2pr	2pr	$0.05	$0.20	Assume 2 pr	$0.20
Gloves, sterile	3pr(6pr if dbl glove)	3pr(6pr if double glo	$0.28	$1.68	Assume 6 pr	$1.68
Irrigation fluid, 1000 cc, sterile	1	1	$1.13	$1.13		$1.13
Monitor Electrodes, EKG	3	3	$0.16	$0.48		$0.48
Needle Counter	1	1	$0.20	$0.20		$0.20
Needle, 18 to 24 guage, local anesth.	1	1	$0.85	$0.85		$0.85
Needle, 25 gauge, disp, local anesth.	2	2	$0.85	$1.70		$1.70
Oxygen, 2-4 liter	unk	unk				
Pedi lap drape	1	1	$4.50	$4.50		$4.50
Peri-Gyn Pack (?)	0	0	$5.04	$0.00		$0.00
PPH Procedural Set	0	1	$389.00	$0.00		$389.00
Scalpie Handle & Blades (2 ea)	1	0	$0.10	$0.10		$0.00
Suction Canister	1	1	$1.42	$1.42		$1.42
Suction Tubing	1	1	$1.36	$1.36		$1.36
Suction tip, Yankauer, disposable	1	1	$1.03	$1.03		$1.03
Surgical cap	8	8	$0.25	$2.00	$12.18 bx/50	$2.00
Surgilube, tube	half	1	$1.08	$1.08	Assume cost of whole tube	$1.08
Syringe, Asepto bulb, disposable	1	0	$0.78	$0.78		$0.00
Syringe, 10 cc.	5	5	$0.15	$0.75	$7.29 bx/50	$0.75
Tape, roll (buttocks)	1	1	$1.00	$1.00		$1.00
Dressing, Telfa, sterile, 8x3	0	0	$0.18	$0.00		$0.00
Towel pack, sterile, 4 per pk	2	2	$1.67	$3.34	Reusable	$3.34
Foam padding, egg crate style (leg support)	2	2	$15.77	$31.54		$31.54
Blankets (hip, shoulder support)	0	2		$0.00		$0.00
lap sponges, sterile, 5 per pack	3	3	$0.53	$1.59		$1.59
Light handle covers (sterile)	3	3	$0.43	$1.29		$1.29
Sutures (3-0 Vicryl or 2-0 Prolene)	5	5	$0.58	$2.90		$2.90
Oxygen saturation monitor (pt connector)	1	1	$3.00	$3.00		$3.00
POSTOP ITEMS						
Mesh suit panties/stretch briefs	1	1	$1.90	$1.90		$1.90
Pain Medication (IV morphine;PO percocet or dilaudid)	pending pt (mg/kg)	pending pt (mg/kg)	$1.00	$2.00	Assume 2 doses @ $1.00/dose	$2.00
Warmed blankets	2	2	$6.75	$13.50		$13.50
			Total:	$184.26		$572.38

Source: Medical Supply Expense Survey - PPH Clinical Sites, 2003. "*Each Prices*" supplied by Deloitte Consulting LLP, April 2004
Note: Procedure labor and overhead are NOT included;
5/24/2005

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Matt Moore
Director
Healthcare Policy and Economics
4545 Creek Road, ML 96
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May 24, 2005

The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
Box 8017
Baltimore, MD 21244-8017

RE: CMS-1478-IFC: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

On behalf of Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company, we are pleased to submit comments for the Interim Final Rule: "Medicare Program; Update of Ambulatory Surgical Center List of Cover Procedures," published in the *Federal Register* on May 4, 2005. We wish to comment on the Proposed Deletions and ask you to consider the removal of CPT 52647 from the ASC Grouper List prior to the final rule going into effect July 1, 2005.

In a letter to CMS dated January 21, 2005 EES recommended deleting CPT code 52647 – Non-contact laser coagulation of the prostate from the Ambulatory Surgery Center (ASC) list. This formal request followed a meeting on March 31, 2004 between Joan Sanow, Bob Cereghino, CMS OPPS staff and EES where it was recommended we submit comments. The reason for our correspondence today is that EES has concerns around the fact that the CPT 52647 ***was not*** removed from the ASC List (p.23754) and CPT 53850 Prostatic microwave thermotx ***was*** deleted (p. 23965).

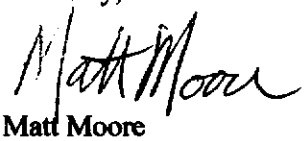
The concern EES has with this decision is two fold:

1) EES markets the Indigo OPTIMA Laser System for treatment of Benign Prostatic Hypertrophy (BPH) – enlarged prostate. The procedure performed is known as interstitial laser coagulation (ILC) of the prostate and coded as 52647. It is one of four types of minimally invasive BPH treatment procedures that collectively are known in the urology community as "prostatic thermotherapy". These four procedures result in essentially the same therapeutic outcome and each has a unique CPT code. The other procedures are: Transurethral microwave themotherapy (TUMT – CPT 53850), transurethral needle ablation (TUNA – CPT 53852), and water induced thermotherapy (WIT – CPT 53853). Furthermore, these therapies (other than CPT 53853), have similar costs and resource utilization associated with the procedure. Based on this we would have expected the Final Rule to have deleted both CPT 52647 and 53850.

2) The proposed deletion of CPT 53850 – Prostatic microwave thermotherapy, in addition to the other thermotherapies not being on the ASC Grouper List, create an uneven playing field. The ILC and TUMT are "like technologies" and have the ability to be performed in any setting of care. These clinical facts were demonstrated in March '05 in our meeting with CMS as EES compared ILC to all thermotherapies using CMS standards (see attachment 1). We also explained how the inclusion of ILC on the ASC List creates financial incentives for providers to use the thermotherapies that are not on the list (see attachment 2). With the latest update of the ASC List of covered procedures, CPT 52647 is now the only thermotherapy with an assigned Grouper. Therefore, if a clinician perceives all things to be equal between the technologies, then the decision on how to treat could be financial due to the reimbursement.

Thank you, for your time and consideration of our comments and recommendations. We look forward to continuing to work with you and your staff in resolving these complex issues.

Sincerely,



Matt Moore
Director – Health Care Policy and Economics

ASTRO
American Society for Therapeutic Radiology and Oncology

JUL - 5 2005

July 5, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1478–IFC
PO Box 8017
Baltimore, MD 21244–8017

Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Dear Dr. McClellan:

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the "Update of Ambulatory Surgical Center List of Covered Procedures" published in the *Federal Register* as an interim final rule with comment period on May 4, 2005. Our comments will address selected surgical procedures associated with the delivery of brachytherapy, a type of cancer treatment where radioactive seeds or sources are placed in or near a tumor to give a high radiation dose to the tumor while reducing the radiation exposure in the surrounding healthy tissues.

Previous Recognition of Brachytherapy on the ASC List of Covered Procedures

In the March 28, 2003 ASC final rule, CMS decided to include CPT code 55859 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) on the ASC list of covered procedures under ASC group nine. ASTRO supported this decision. CPT code 55859 represents the surgical portion of prostate brachytherapy. Prostate brachytherapy is the temporary or permanent implantation into the prostate for the treatment of prostate cancer. It may be performed as a permanent "seed" type or as a high dose rate (HDR) afterloading temporary procedure. Section 621(b) of the Medicare Modernization Act (MMA) amended section 1861(t) of the Social Security Act to require separate payment for devices of brachytherapy (seeds or radioactive sources) under the outpatient prospective payment system. The cost of the permanently implanted radioactive seeds must be reimbursed to the purchasing entity with the appropriate regulatory authority and licenses. At the hospital facility, payment is according to the hospital's charges for each device furnished, adjusted to cost. Since ASCs are not paid under this methodology, ASTRO recommends that payment be made based on invoice cost.

Expansion of Brachytherapy on the ASC List of Covered Procedures

Since the 2003 final rule when CMS approved prostate brachytherapy (CPT code 55859), ASTRO has expressed support for adding other brachytherapy codes to the ASC list so that physicians have the option, and the patients have the convenience, of performing other brachytherapy procedures in an ASC setting. In the 2005 interim final rule, CMS indicated that the agency had received comments from this year's proposed rule requesting that the

[1] ASTRO is the largest radiation oncology society in the world, with more than 8,000 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.

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surgical procedures associated with brachytherapy for cancer of the breast, cervix, vagina and uterus also be added to the list of covered ASC procedures. ASTRO supports these additions. However, CMS did not accept all the recommendations made by several organizations and assigned payment groups for several of the codes that ASTRO believes will be inadequate to cover the costs of providing the services. In addition, unless the reimbursement accounts for the costly supplies (radioactive materials, balloon applicators, perineal templates, needles and catheters etc.) that are required to perform these procedures, access to the services the agency intended to provide by adding the codes to the list of covered procedures will not be available. Examples are described under individual code sections. The subject of this communication is the complete reimbursement for services provided at an ASC related to brachytherapy. They include the surgical procedure and the catheters, needles, and other special devices, related to brachytherapy.

Please refer to Attachment A for a table that lists the codes for the surgical portion of brachytherapy services that were recommended for inclusion on the ASC list, the CMS decisions and ASTRO's positions on these decisions. For those codes and payment groups where we disagree with the CMS decisions, a detailed explanation of our rationale and our recommendations are provided below.

1. CPT Code 19296 *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy*

In the interim final rule, CMS accepted a commenter's recommendation to include CPT code 19296 on the ASC list. Cost data in the CMS file on practice expenses that were developed with the assistance of the AMA's Relative Value Scale Update Committee (RUC) documents a cost of $2550 for the catheter. Clearly, this procedure will never be performed in an ASC if the total payment will be only $1339 and the cost of the catheter alone is approximately $2600.
Additional rationale to support separate payment may be found in the CMS outpatient hospital payment decision that assigned code 19296 to APC 1524 New Technology - Level XIV. This APC has a payment rate of $3250 under the outpatient prospective payment system (OPPS) for calendar year 2005.

Until such time as the ASC payment methodology is revised in accordance with the Medicare Modernization Act (MMA), we believe the simplest and best way to assure adequate payment for this procedure is to make separate payment for the balloon catheter. Since the volume of procedures is not expected to be high, we believe that documentation of cost through submission of invoices would be a good method to assure appropriate payments for the catheters.

Therefore, ASTRO supports CMS's decision to include CPT code 19296 on the ASC list and assigning it to the highest paying group (Group 9 at $1339). However, we urge CMS to issue instructions to permit separate payment for the balloon catheter that is inserted during the procedure.

2. CPT Code 19297 *Placement of radiotherapy afterloading balloon catheter, concurrent with partial mastectomy (List separately in addition to code for primary procedure)*

CMS rejected the recommendation to include this code on the ASC list because it is an "add-on" procedure that is included in another procedure and not typically performed on its own. CMS stated in the interim final rule:

> *We do not typically approve this type of procedure for addition to the ASC list as the facility costs for the additional work included in the procedure is not usually significant. That is, the resources required to perform a procedure with or without also performing an 'add-on' procedure are not significantly different. Time in the operating suite, supplies, and other resources that Medicare pays for in the ASC, are not significantly increased by performance of the additional procedure. Therefore, under the current rate-setting method, we cannot accurately identify a separate price for 'add-on' procedures.*

We agree that there are some add-on procedures for which the facility costs for the additional work included in the procedure is not significant, e.g., code 35390 (Reoperation, carotid, thromboendarterectomy, more than one month after original operation (List separately in addition to code for primary procedure). However, in the case of breast brachytherapy, the CMS rationale for excluding code 19297 from the list is inconsistent with the reality of the added significant balloon catheter costs. . To the extent that partial mastectomy is an appropriate procedure performed at an ASC, it is reasonable to allow and reimburse for the placement of the balloon brachytherapy catheter at the same time (as may already be done in the hospital setting).
Excluding code 19297 will either reduce access to this procedure in the ASC setting for those women who could benefit from the procedure or increase the cost by requiring a separate procedure.

We believe that CPT code 19297 should be included on the list of covered ASC procedures and its assignment to payment group 9, which has a payment rate of $1,339. This would be consistent with the appropriate CMS decision to assign similar code 19296 to payment group 9. Both procedures involve the use of the expensive balloon catheter and data on physician time collected for the physician fee schedule indicates that both procedures require 30 minutes of intra-operative times.

Additional rationale to support separate payment may be found in the CMS outpatient hospital payment decision that assigned code 19297 to APC 1523 New Technology - Level XIII. This APC has a payment rate of $2,750 under the outpatient prospective payment system (OPPS) for calendar year 2005.

Therefore, ASTRO recommends inclusion of CPT code 19297 on the list of covered ASC procedures. However, ASTRO strongly recommends that it be assigned to the highest paying group (Group 9 at $1339). As discussed above for code 19296, we believe separate payment for the catheter should be made to assure access to the procedure in an ASC.

3. CPT Code 19298 *Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy*

We support the decision to include this procedure on the list of covered ASC procedures. However, we believe an error has been made in assigning the code to payment group 1 which has a payment rate of only $333. We recommend assigning the code to payment group 9 with a payment rate of $1339.

According to the data on physician time collected for the physician fee schedule, this procedure typically is twice a long (60 minutes of intra-operative time) with codes 19296 and 19297. The placement of multiple tubes and buttons (typically 25-35 individual catheters) is far more complex and intricate a procedure than the placement of a single balloon catheter. In addition, the cost of the multiple tube and button type afterloading brachytherapy catheters is considerable.

Cost data in the CMS file on practice expenses that were developed with the assistance of the AMA's Relative Value Scale Update Committee (RUC) documents a cost of $555 for 30 single leader implant catheters that cost $19 each. Our cost survey indicates these catheters are $23 each and the buttons are $2 each. Thus for 30 catheters the costs would be at least $750. New and improved catheters are even more expensive but they provide patients with greater "comfort" during treatment. The 30 catheter system costs approximately $3000 Clearly, this procedure will never be performed in an ASC if the total payment will be only $1339 We suggest that since the number of catheters per patient varies considerably according to the size of the implant (much like prostate brachytherapy), it would be advisable to create an invoice related payment system for these devices.

Additional evidence to support separate payment may be found in the CMS outpatient hospital payment decision that assigned code 19296 to APC 1524 New Technology - Level XIV. This APC has a payment rate of $3250 under the outpatient prospective payment system (OPPS) for calendar year 2005.

Therefore, ASTRO supports CMS's decision to include CPT code 19298 on the ASC list. However, ASTRO strongly recommends that it be assigned to the highest paying group (Group 9 at $1339). For the same reasons indicated for codes 19296 and 19297, we believe that separate payment for the catheters must be made to assure access to the procedure in an ASC.

4. CPT Codes 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* and 58346 *Insertion of Heyman capsules for clinical brachytherapy*

We support the decision to include these procedures on the list of covered ASC procedures. However, we believe an error has been made in assigning the codes to payment group 1 which has a payment rate of only $333. We recommend assigning the code to payment group 9 that has a payment rate of $1,339.

According to the data on physician time collected for the physician fee schedule, codes 57155 and 58346 typically requires 55 and 60 minutes of intra-operative time, respectively. In addition, the costs of the devices that are placed to deliver the brachytherapy (uterine tandems, vaginal ovoids or Heyman capsules) are expensive.

For code 57155, tandem and ovoid (or similar tandem and ring) applicator set is used required. These devices come in one time use and reusable formats. Our survey for the reusable set indicates that the cost is approximately $12,500. While some parts of this set are reusable, the non-reusable parts should be separately paid. In the case of disposable applicator systems the entire set should also be paid separately. For code 58346, the Heyman or Norman-Simon capsules cost approximately $86 each and the introducers costs $46 each. For a typical patient who might require 10 applications, the total cost of the capsules and introducers is approximately $1,300.

Therefore, ASTRO supports CMS's decision to include CPT codes 57155 and 58346 on the ASC list. However, ASTRO strongly recommends that these codes be assigned to the highest paying group (Group 9 at $1339). As discussed above for codes 19296, 19297 and 19298, separate payment for the supplies should be made to assure access to the procedures in an ASC.

Payment Options Related to Brachytherapy Furnished in an ASC

In the interim final rule, CMS indicates that the agency is "currently trying to resolve a number of payment options related to the performance of prostate brachytherapy and the extent to which those services could be paid for when furnished in an ASC under existing regulations related both to ASCs and other payment systems such as the Medicare physician fee schedule." We agree that the issues are complex and we note that the addition of the addition of the surgical procedures associated with brachytherapy for cancer of the breast and uterus to the ASC list makes the issues even more complex. We hope you will agree that they can all be resolved affirmatively.

We would be pleased to work with your staff in the development of instructions that will assure appropriate access to care and payment for brachytherapy services. We believe a reasonable starting point for discussions can be found in the preamble of the 1998 proposed rule on ASCs.[2] CMS acknowledged that code 55859 represents only the surgical component to prostate brachytherapy treatment and stated:

"The other procedures and services performed to furnish this treatment fall within the radiology range (70,000-79,999) of CPT®. Since radiology procedures are not included on the ASC list, there is no basis for Medicare to make payment to an ASC for brachytherapy service. However, if the facility were to obtain supplier numbers from its carrier indicating that the carrier recognizes the facility both as a non-physician supplier of radiology services and as a freestanding radiation therapy center, the facility should be able to bill for and be paid the technical component for brachytherapy services within the radiology range under the Medicare physicians' fee schedule. Similarly, if a Medicare approved ASC were to furnish diagnostic X-ray and other diagnostic test in connection with performing a procedure on the ASC list, such as visualizing the preoperative placement of needle

[2] Federal Register. Vol. 63, No. 113. June 12, 1998. page 32314.

localization wires, and if payment for those services is not otherwise included in the ASC facility fee as signified by an ASC payment policy indicator "2", the facility could be paid the technical component provided for those services under the Medicare physicians' fee schedule as long as it meets the requirements for independent diagnostic testing facilities (IDTFs)."

In addition, we would like to bring to your attention the fact that sound and workable policies have been developed at the local carrier level. These local policies should be considered during your development of national policies.

Future ASC Changes

Section 626(b) of MMA requires CMS to implement a revised payment system between January 1, 2006 and January 1, 2008 that takes into account recommendations in the report to the Congress that was to be submitted by January 1, 2005 by the Comptroller General of the United States. As you work on the implementation of the new system, we ask that you carefully consider the potential impact of the new system on brachytherapy. For example, a decision to pay ASCs at a some percentage of the APC payments under the outpatient prospective payment system could adversely impact services such as brachytherapy that typically involve high supply or device costs. These costs are generally the same across the country and often are not available at discounted prices. Thus, a uniform discount off the APC rates could create significant problems. A second example relates to permanent seed prostate brachytherapy. Under OPPS, these seeds are separately paid. In our opinion, as indicated before, a new ASC payment policy must allow the same opportunity for separate payment because the variability in the number if seeds precludes the development of a workable and equitable prospective payment rate.

Conclusion

Thank you for this opportunity to comment on this proposed rule. We look forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Ms. Trisha Crishock, Director of Health Care Policy & Economics at 800-962-7876 for further information.

Sincerely,

D. Jeffrey Demanes, M.D.
Chair, ASTRO Regulatory Subcommittee

cc: Dana B. Burley
Louis Potters, M.D.
Timothy R. Williams, M.D.
Michael L. Steinberg, M.D.

American Urological Association

JUL - 5 2005

July 1, 2005

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: CMS-1478-IFC, Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures.

Dear Dr. McClellan:

On behalf of the American Urological Association, I request that CMS delete two procedures from the ambulatory surgical center (ASC) list of covered procedures that went into effect on July 1, 2005:

- CPT code 52647, *Non-contact laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*
- CPT code 55873, *Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)*

It has been the AUA's position for some time (see attached letter from October 2002, pages 2-5), that these procedures should not be on the ASC list under the current payment system, which does not cover the costs of performing the procedures in an ASC. Unfortunately, placing these procedures on the ASC list under the current payment system will have unintended negative consequences as outlined below.

CPT code 52647

CPT code 52647, also known as interstitial laser coagulation (ILC), is a heat therapy procedure used to treat benign prostatic hyperplasia (BPH). Similar to CPT code 53850, *Transurethral destruction of prostate tissue; by microwave thermotherapy (TUMT)*, which CMS deleted from the list as of July 1, CPT code 52647 requires resources to perform the procedure that significantly exceed the highest ASC facility fee. We urge CMS to also delete CPT code 52647 off the list until a new ASC payment system is developed in 2008.

Headquarters

Michael T. Sheppard, CPA, CAE
Executive Director

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Although ILC is performed on Medicare patients in a physician's office almost half of the time, deleting it from the ASC list will actually assure that the ASC site-of-service is available to Medicare beneficiaries, as is also the case with CPT code 53850, a prostate heat therapy treatment that uses microwave heat. For these procedures, because they have high-cost in-office disposable supplies, leaving them off the ASC list and allowing physicians to bill for the in-office (non-facility) payment rate when performed in an ASC (which is the CMS policy for procedures that aren't on the ASC list) will ensure that Medicare beneficiaries will have access to this procedure in the ASC setting if necessary.

Now that CPT code 53850 will be deleted from the list, it has come to our attention that Medicare beneficiaries may not be free to choose between these two procedures in the ASC setting, as ASCs will be able to recover their costs for 53850, but not for 52647.

If the code is deleted from the ASC list, the physician could set up an agreement with the ASC to perform the procedure there, bill the non-facility rate and then return part of the fee to the ASC via a contract that complies with fair market value requirements. These types of contracts exist for other BPH heat therapy treatments, including CPT 53850 and 53852, and maintaining CPT code 52647 as the only heat therapy treatment on the ASC list will restrict beneficiaries from choosing this treatment option in an ASC.

CPT code 55873

CPT code 55873, cryosurgery of the prostate, also requires resources to perform the procedure that significantly exceed the highest ASC facility fee of $1,339, with the cost of the cryoprobes and urethral warmer alone approaching $5,000. Furthermore, if private insurance companies begin to adopt the Medicare payment rate, it could jeopardize the ability of non-Medicare patients to receive cryosurgery of the prostate in an ASC.

In addition, we do not feel that this decision has been properly vetted, as CMS made the decision based on one commenter's request and also did not announce the addition until June 24 when it appeared in a correction notice to the May 4 interim final rule.

For these reasons, we urge CMS to delete CPT code 55873 from the ASC list until the payment system is revised.

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, AUA Regulatory Affairs Manager, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

James B. Regan, M.D.
Chair, Health Policy Council

Attachment

Attachment.

American
Urological
Association, Inc.®

October 14, 2002

Ms. Joan Sanow
Department of Health and Human Services
Center for Medicare and Medicaid Services
MS C4-03-18
7500 Security Blvd.
Baltimore MD 21244-1850

Dear Ms. Sanow:

On behalf of the American Urological Association (AUA) and its 10,000 members, I am writing in anticipation of a final rule on the ambulatory surgical center (ASC) payment system soon to be published by the Centers for Medicare and Medicaid Services (CMS). As we understand it, this rule would finalize parts of the June 12, 1998 proposed rule—HCFA-1885-P. For your information, I have included a copy of the AUA's proposed-rule comments.

We understand that the final rule will deal only with the addition and deletion of CPT codes from the Medicare ASC list of covered services, and will not address payment rates. We agree that there are many procedures that should be added to the ASC list, but are disappointed with CMS's policy decision to determine whether to add or delete CPT codes from the ASC list outside the context of proper payment.

With these constraints in mind, we offer the following recommendations for the ASC list. These recommendations are based on which procedures can be safely and effectively performed in an ASC and which ones would actually be performed in an ASC considering the current 9 payment groups. CMS should not place procedures on the ASC list if they cannot be adequately reimbursed in an ASC, as this really accomplishes nothing. Because of this, we urge CMS to begin paying for ASC services using the ambulatory payment classification system (as proposed in 1998) as soon as possible.

We offer three categories of CPT codes for your consideration:

1. CPT codes that have been created since 1998 that should be on the ASC list

2. CPT codes that have been created since 1998 that should not be on the ASC list until the payment system is adjusted

3. CPT codes that were proposed to be added to the ASC list in 1998 that should not be on the list until the payment system is adjusted

1. **CPT codes that have been created since 1998**

Table I shows procedures that have received a new CPT code since release of the June 12, 1998 proposed rule that can be safely and effectively performed in an ASC and that could be reimbursed adequately using the current 9 payment groups.

CPT Code	Descriptor	Globe	New In...
11981	Insertion, non-biodegradable drug delivery implant	XXX	2002
11982	Removal, non-biodegradable drug delivery implant	XXX	2002
11983	Removal with reinsertion, non-biodegradable drug delivery implant	XXX	2002
54406	Removal of all components of a multi-component, inflatable penile prosthesis w/o replacement of prosthesis	90	2002
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, w/o replacement of prosthesis	90	2002
54522	Orechiectomy, Partial	90	2001

2. **CPT codes that have been created since 1998 that should not be on the ASC list until the payment system is adjusted**

Table II shows procedures that have received a new CPT code since release of the June 12, 1998 proposed rule that could be safely and effectively performed in an ASC. While we agree conceptually that these services can be performed in ASC settings, the proposed payment levels are grossly inadequate. In fact, for a number of procedures, the current ASC payment rates will not cover the cost of the disposable supplies. Unless the payment rate is substantially increased, these procedures will not be performed in an ASC setting. Therefore, it makes little sense to add these procedures to the ASC list until such time as the ASC payment rates are revised to provide for payment substantially above the current rate assigned to Group 9 services.

CPT Code	Descriptor	Globe	New In...
50021	Drainage of perirenal or renal abscess; Percutaneous	0	1998
50949	Unlisted laparoscopy procedure, ureter	YYY	2001
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	90	2000
51992	Laparoscopy, surgical; sling operation for stress incontinence (eg, fascia or synthetic)	90	2000
52341	Cystourethroscopy with treatment of ureteral stricture (eg, balloon dilation, laser, electrocautery, and incision)	0	2001
52342	Cystourethroscopy with treatment of ureteropelvic junction stricture (eg, balloon dilation, laser, electrocautery, and incision)	0	2001
52343	Cystourethroscopy with treatment of intra-renal stricture (eg, balloon dilation, laser, electrocautery, and incision)	0	2001
52344	Cystourethroscopy with ureteroscopy; with treatment of ureteral stricture (eg, balloon dilation, laser, electrocautery, and incision)	0	2001
52345	Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (eg, balloon dilation, laser, electrocautery, and incision)	0	2001
52346	Cystourethroscopy with ureteroscopy; with treatment of intra-renal stricture (eg, balloon dilation, laser, electrocautery, and incision)	0	2001
52347	Cystourethroscopy with transurethral resection or incision of ejaculatory ducts	0	2002
53853	Transurethral destruction of prostate tissue; by water-induced thermotherapy, 090: proposed	90	2002
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis	90	2002
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session	90	

CPT Code	Descriptor	Globe	New In...
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session	90	2002
54690 (formerly 56318)	Laparoscopy, surgical; orchiectomy	90	2000
54699	Unlisted laparoscopy procedure, testis	YYY	2000
55550	Laparoscopy, surgical, with ligation of spermatic veins for varicocele	90	2000
55559	Unlisted laparoscopy procedure, spermatic cord	YYY	2000
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)	90	2001
57287	Removal or reversal of sling for stress incontinence (eg, fascia or synthetic)	90	2001
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)	10	2002
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)	10	2002

3. CPT codes that were proposed to be added to the ASC list in 1998 that should not be on the list until the payment system is adjusted

Table III shows three CPT codes that were proposed to be added to the ASC list in 1998, but that also will not be performed in an ASC under the current 9 payment groups. In fact, the costs of the disposable supplies alone approximates the entire ASC rate, which is intended to cover clinical and administrative staff costs, supplies, equipment and ASC overhead. Also, these procedures currently have in-office practice expense rates under the physician fee schedule that substantially exceed the highest ASC payment category. We further note that the American Medical Association's Practice Expense Advisory Committee is going to be validating the practice expenses for these three codes in the next few months. We urge CMS not to add these codes to the ASC list since the procedures will not be performed in that setting at current rates. Rather, you may want to consider the PEAC's determination of costs for future consideration of appropriate ASC rates for these services.

CPT Code	Descriptor
52647	Non-contact laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy

Thank you for considering our suggestions for the ASC list. If you have any questions or need additional information, please contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-223-4325 or rhudson@auanet.org.

Sincerely,

Winston K. Mebust, M.D.
President

cc: Bob Cereghino, CMS
William F. Gee, M.D., AUA Health Policy Council Chairman
Cherie McNett, AUA Government Affairs Director

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June 30, 2005

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Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Attention: CMS-1478-IFC

Dear Dr. McClellan,

We are writing in response to the Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures Interim Final Rule with Comment Period published in the May 4, 2005 Federal Register Vol. 70, No. 85.

AKSM/Ortho, Inc. (Ortho) is a provider of High Energy Extracorporeal Shock Wave (ESW) in twenty-one states to patients with chronic plantar fasciitis. Ortho is submitting this comment requesting the addition of High Energy ESW involving the plantar fascia to the Ambulatory Surgical Center List of Covered Procedures (ASC List). This request is directly related to the forthcoming Category I CPT Code 2825X, which is currently listed as CPT Code 0020T. We have been informed that this Category I Code will be published effective January 1, 2006.

Physicians have performed thousands of ESW procedures over the past five years in the United States. The vast majority of these procedures have been performed in ASC's. The following factors detail why the physician providers prefer that this procedure is performed in an ASC setting:

- ✓ Anesthesia Requirements: High Energy ESW requires "anesthesia other than local" as stated by the American Medical Association's CPT Editorial Panel. The procedure requires a regional nerve block which is a higher level of anesthesia than is typically performed in an office setting. In addition, because of the required level of anesthesia, some physicians prefer administering ESW with minimal resuscitation availability. However, we recognize the minimally invasive nature of this procedure and acknowledge that significant applications of anesthesia typically used in the outpatient hospital setting are not necessary. Nevertheless, the anesthesia requirement falls within what is comfortably administered in an ASC.

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Scheduling: 866-260-9780 • www.AKSM.com

- ✓ Facility Overhead: High Energy ESW does not require extensive overhead such as that found in a hospital setting. One ESW procedure lasts around thirty minutes, including patient preparation, anesthesia, and treatment. The lesser ASC capabilities are suitable for this procedure. We have found that the patients feel comfortable with the security afforded by the ASC environment.

- ✓ Equipment Design and Cost: The equipment associated with High Energy ESW was designed for mobile transport. As such, the equipment is optimized for utilization within ASC's. In addition, the cost of the equipment is several hundred thousand dollars. Thus, efficient utilization of the equipment is absolutely necessary to ensure Medicare beneficiaries everywhere can take advantage of the benefits of this technology. ASC's are designed to ensure efficient utilization of High Energy ESW equipment.

Recently, nineteen companies which provide High Energy ESW collaborated with Aequitas, a leading health care advisory firm that specializes in evidence-based product valuation, to create a cumulative health technology assessment and health economic analysis for High Energy ESW involving the plantar fascia. This assessment indicated that greater than 90% of all High-Energy ESW procedures are performed in an ASC setting.

As such, it is imperative that High Energy ESW involving the plantar fascia be included in the Medicare Ambulatory Surgical Center List of Covered Procedures. Specific anesthesia requirements, overhead necessities, and the minimally invasive nature of this procedure have already driven the market to perform this procedure primarily in an ASC setting. Without High Energy ESW, which has a short and generally complication free recovery period of several days, Medicare beneficiaries will continue to be subjected to invasive surgeries requiring significant, inconvenient recovery periods.

For these specific reasons, we would like to formally request the addition of High Energy ESW involving the plantar fascia to the Ambulatory Surgical Center List of Covered Procedures (ASC List).

We are aware that procedures that do not have active Category I Codes are not typically added to the ASC List. As noted above, the AMA is proposing a Category I CPT Code for High Energy ESW involving the plantar fascia. This new code, 2825X, is proposed to be effective January 1, 2006 and will replace the existing CPT Code 0020T. If 0020T code is not to be added to the ASC List immediately, and 2825X cannot be added until it reaches full Category I status, we ask that 2825X be added to the ASC List as soon as it is published as Category I on January 1, 2006. In doing so, Medicare

beneficiaries can avail themselves of ESW instead of being subjected to undesirable and more costly open surgery.

Thank you for the opportunity to comment on CMS-1478-IFC. We look forward to working with CMS to address our concerns.

Sincerely,

John Furia, M.D.
Medical Director
AKSM/Ortho, Inc.
614-298-8150

RPA
Renal Physicians Association

JUL - 5 2005

June 30, 2005

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Attn: CMS 1478-IFC
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington DC 20201

Delivery Address:
Department of Health and Human Services
Attn: CMS-1478-IFC
PO Box 8017
Baltimore MD 21244-8017

RE: Update of the Ambulatory Surgery Center List of Covered Procedures (CMS-1478-IFC) Interim Final Rule

Dear Dr. McClellan:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease.

RPA is writing to address the removal of CPT codes 37205, 37206, 35475, and 35476 from the list of Medicare approved additions to the list of procedures covered in the ambulatory surgical center (ASC). We are writing to support the comments of the American Society of Diagnostic and Interventional Nephrology (ASDIN) and others opposing the removal of these codes from the ASC approved list.

In the final rule CMS notes, *"we received many comments in support of the proposed additions to the ASC list. However, we received one comment that opposed the additions of CPT codes 37205, 37206, 35475, and 35476. The commenter stated that these procedures were not appropriate for the ASC setting and would allow for potential substandard care."*

RPA disagrees with this comment in the strongest possible terms. There is substantial literature that has been provided by ASDIN to CMS refuting the notion that these services are inappropriate for the ASC setting, and, rather than allowing for potential substandard care, provision of these

services in the ASC setting represents a significant advance in patient care due to the elimination of unnecessary hospitalizations. Further, provision of these services in the ASC setting would promote efficient use of the Medicare health care dollar and would support the goals of CMS' own Fistula First program, which aims at having fistulas placed in at least half of all new dialysis patients, with a long-range goal of maintaining fistulas in 40 percent of eligible patients who remain on dialysis. Currently, only about 30 percent of Medicare beneficiaries dialyze with a fistula.

For these reasons, RPA strongly urges CMS to reinstate CPT code 37205, 37206, 35475, and 35476 to the list of Medicare approved procedures covered in the ambulatory surgical center (ASC).

As always, we welcome the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's ESRD patients, and we stand ready as a resource to CMS in its future endeavors.

Sincerely,

Robert Provenzano, M.D.
President

19

Medtronic
XOMED

JUL - 5 2005

Medtronic USA, Inc.
6743 Southpoint Dr. N.
Jacksonville, Florida 32216-0980

tel 904.296.9600

June 28, 2005

Via U.S. MAIL

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: Comments to **CMS-1478-IFC**

Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures -- Analysis of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of This Interim Final Rule With Comment Period

D. Procedures Requested for Addition in Comments

Dear Administrator McClellan:

On January 19, 2005, Medtronic sent a letter commenting on the proposed rule updating the list of Medicare approved ASC procedures. Medtronic requested that Current Procedural Terminology (CPT)[1] code 61795 for computer assisted surgical navigation (CASN) procedures be added to the list of approved ASC procedures. While we appreciate CMS's consideration of this request, we are disappointed in the decision not to add this code and urge you to reconsider.

Interim Final Rule

As stated on page 23699 of the final rule, the reasoning for not adding 61795 to the list of approved ASC procedures is:

> "CPT code 61795 is for coding the use of equipment, is not a surgical procedure, and is therefore, not an appropriate addition to the ASC list. We will not add this to the ASC list of covered procedures."

We feel the decision not to add code 61795 was misguided. It may reflect a lack of familiarity with the nature of CASN, also known as image-guided surgery (IGS). More directly, the

[1] CPT is a trademark of the American Medical Association (AMA).

decision not to add 61795 to the ASC list of covered procedures does not take into account issues of decreased access to ASCs for Medicare beneficiaries as well as the resulting increased costs to the Medicare program.

Nature of Computer Assisted Surgical Navigation

The rule states that code 61795 is for "coding the use of equipment" and "is not a surgical procedure." This statement is untrue.

CASN is not a scalpel or a radiofrequency generator. It is an adjunctive surgical process in which real-time imaging is integrated into the primary procedure, impacting the surgical approach as well as the extent and completeness of the primary procedure. The procedure involved in CASN requires the additional use of ASC resources in operating room time and technical staff support as well as the financial investment of purchasing the CASN system. Even though the primary surgical procedure time may be the same, the overall operating room time may be increased. This increase in resource consumption justifies the need for reimbursement to the ASC for the CASN procedure.[2] Use of CASN results in substantially different surgical methodology and a unique procedure compared to the same operation performed conventionally.

Over the past 10 – 15 years, numerous peer-reviewed clinical papers have reinforced the procedural benefits of CASN. Olson and Citardi[3] in their study pronounced, "images provided by surgical nasal endoscopy and CASN together affect the surgical technique, strategy, and philosophy." Regarding the specific utility of CASN, Olson and Citardi state "...CASN allows surgeons to perceive spatial relationships with a sense of depth previously unobtainable by viewing static films. [CASN] enables surgeons to comprehend spatial relationships both more directly and more accurately."

New ICD-9-CM procedure codes for CAS became effective October 1, 2004, reflecting the consensus that CASN represents a significant, meaningful adjunctive surgical procedure.

In the course of other interactions with CMS, we have understood that procedures eligible for inclusion on the ASC list of covered procedures are those in the Surgery section of CPT. Although this perspective may be debated, the fact remains that code 61795 is indeed located in the Surgery section of CPT. Moreover, the American Medical Association (AMA) granted a category I code for it because it is a procedure that is consistent with contemporary medical practice and performed by surgeons in clinical practice in multiple locations.[4] As you know, the AMA grants CPT codes only for procedures or services and not for the mere use of a certain piece of equipment.

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[2] Fried, Marvin P, et al: Comparison of endoscopic sinus surgery with and without image guidance. American Journal of Rhinology July/August 2002; (16)4: 193-197

[3] Olson G, Citardi MJ: Image-guided functional endoscopic sinus surgery. Otolaryngol Head Neck Surg 2000; 123:188-94.

[4] *See* AMA CPT Background and Categories of CPT Codes, available at http://www.ama-assn.org/ama/pub/category/12886.html.

Medicare Beneficiary Access

Continuing to omit the code 61795 from the list of covered procedures prevents the ASCs from receiving the reimbursement necessary to provide CASN to Medicare patients. The lack of reimbursement may result in the Medicare patients being diverted to hospital outpatient surgical departments creating an access barrier for Medicare beneficiaries in the ASC setting.

There is a portion of the Medicare beneficiary population that, due to clinical status or geographic location, is well-served by having a variety of procedures available in an ASC. If CASN is not provided in this setting, the scope of procedures available to these beneficiaries is necessarily reduced.

CASN is not needed in many procedures. For those in which the surgeon determines its use is appropriate, however, it constitutes a key component of the operation. Without it, surgeons can be reluctant to proceed in the ASC, although it would otherwise be the safest and most appropriate setting for the procedure. For example, Reardon,[5] in a comparative study of sinus surgery involving 800 procedures (400 without CASN and 400 with CASN) showed a significant increase in the number of frontal sinusotomies possible with CASN and no major navigational complications.

It must also be noted that CASN actually improves the safety of procedures in which the surgeon elects to use it. CASN allows a surgeon to discriminate patient anatomy precisely and to access anatomy that is difficult to find or to reach. By enabling precise trajectories and identifying the location of surgical instruments relative to patient anatomy, it substantially minimizes trauma and secondary damage to the patients. In the study by Reardon,[2] there were no major navigational complications using CASN while the standard approach, without CASN, did result in complications associated with the surgical approach. In essence, in the patient group without CASN the surgeon inadvertently penetrated into areas outside the desired operative field i.e. outside the sinuses (1 retro-orbital hemorrhage, 2 CSF leaks). In the patient group with CASN, there were no such "navigational" errors. The clinical judgment of the surgeon that CASN is an appropriate surgical adjunct should not be impeded by restrictions on its availability in the ASC setting.

Providing payment for CASN in the ASC setting ensures that Medicare beneficiaries will be afforded the same access and benefits of ASC treatment as private sector patients.

Increase in Cost to the Medicare Program

When a surgeon determines that use of CASN is appropriate but it is unavailable in the ASC setting, the procedure will have to be performed in the hospital outpatient setting.

CPT code 61795 is classified as a significant procedure and is separately payable under Medicare's prospective payment system for hospital outpatient services (OPPS). Under the OPPS, separate payment is made not only for CASN and the other procedures but also for

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[5] Reardon EJ: Navigational Risks Associated With Sinus Surgery and the Clinical Effects of Implementing a Navigational System for Sinus Surgery. Laryngoscope 2002; 112:1-19.

ancillary services such as laboratory, EKG and radiology. Moreover, the level of payment itself is often higher.

Not providing payment for CASN in the ASC setting creates an incentive to perform procedures in other settings that are less appropriate for Medicare beneficiaries and more costly to the Medicare program. For these reasons, we again request that CMS add CPT code 61795 for CASN to the Medicare ASC approved list.

We appreciate the opportunity to comment on the interim final rule. If you have questions or desire additional information on our comments, please contact me at (904) 279–7569.

Sincerely,

Kim Brew
Manager of Reimbursement and
Therapy Access

JUL - 5 2005

Southwestern Group, Ltd.

500 Lewis Run Road • Pittsburgh, PA 15122

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ASSISTED CARE RESIDENCE
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ARROWOOD AT SOUTHWESTERN
Phone:
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(412) 469-8633

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: 42 CFR Part 416

To Whom it May Concern:

I am the C.F.O. of the Southwestern Ambulatory Surgery Center, who is writing to you in regards to the laparoscopic cholecycstectomies and other laparoscopic procedures relating to the interim final rule for the update of the ambulatory surgical center list of covered procedures. We have suffered great financial hardship to our facility, due to the ruling on laparoscopic procedures, especially not being able to due laparoscopic cholecycstectomies at our surgery center. Most ambulatory surgery centers have a proven track record for many years of extremely low complications in all procedures and very high patient satisfaction. Their laparoscopic surgeons are very well trained in these procedures and utilize strict patient selection criteria to choose patients who are appropriate candidates for these surgeries at ASC's. The outcomes have been better than that at most hospitals because of their strict guidelines and emphasis on patient safety at Southwestern Ambulatory Surgery Center (SWASC), located in Pittsburgh, PA.

We have evidence that the freestanding facility follows as stringent if not more stringent safety protocols because they are not part of a hospital building. They have all of the same emergency equipment in the event that the procedure would need to be converted to an open procedure or in the event of a cardiac arrest. It is NOT a substantial risk that the laparoscopic approach will not be successful and that conversion to an open procedure will be necessary. In the 5 years that our facility has been performing all laparoscopic cases, we have NEVER converted any of our cases to an open procedure. In fact in published data, the actual rate of conversion is much lower at ASC's than at hospitals due to our strict selection criteria. Even if a patient did need an open procedure, we are always prepared for that possibility and the procedure would be completed and the patient then transferred to the hospital according to our usual transfer protocols.

At ours and most ambulatory surgery centers, the entire nursing and anesthesia staff members are ACLS trained, which is not the case in many hospitals. SWASC is also located less than one mile from Jefferson Regional Medical Center with whom we have a transfer agreement. A patient could be transferred to the emergency room in the same time it would take most hospitals to transfer a surgical patient from their OR

to their ICU. It is an injustice to patients in this geographic area who have had to postpone their surgeries and be scheduled at other hospitals due to SWASC's current restriction. It is also a financial hardship on SWASC to not be permitted to perform these due to the large capital expenditure that was needed to purchase the equipment and to train all OR personnel.

Please seriously consider rescinding these restrictions on ambulatory surgery centers. They are known to follow all of the state and federal regulations regarding length of surgery, anesthesia and recovery room time. The current PA-PSERS program will be very helpful in tracking facilities with higher than average complication rates. Thank you for your consideration in this matter.

Sincerely,

William Henry
Chief Financial Officer, Southwestern Group, Ltd.

Spartan Health Surgicenter
100 Stoops Drive
Monongahela, PA 15063

JUL - 5 2005

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

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Sincerely,

Giovanna Zanardelli, R.N.
Director of Nursing
Spartan Health Surgicenter

JUL - 5 2005

BPW MEDICAL ASSOCIATES, P.C.
1524 HIGH ROAD
JEFFERSON HILLS, PA 15025

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: 42 CFR Part 416

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I am a C.R.N.A., who is writing to you in regards to the laparoscopic cholecycstectomies and other laparoscopic procedures relating to the interim final rule for the update of the ambulatory surgical center list of covered procedures. Most ambulatory surgery centers have a proven track record for many years of extremely low complications in all procedures and very high patient satisfaction. Their laparoscopic surgeons are very well trained in these procedures and utilize strict patient selection criteria to choose patients who are appropriate candidates for these surgeries at ASC's. The outcomes have been better than that at most hospitals because of their strict guidelines and emphasis on patient safety at Southwestern Ambulatory Surgery Center (SWASC), located in Pittsburgh, PA.

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Sincerely,

Barbara Banasick

Barbara Banasick, C.R.N.A.
B.P.W. Medical Associates

PHILIP P. RIPEPI, M.D., F.A.C.S.
ANTONIO J. RIPEPI, M.D., F.A.C.S.
Southwestern Surgical Associates, P.C. • Suite 101
500 Lewis Run Road • Pittsburgh, PA 15122
412/466-4121 • FAX: 412/469-2633

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: 42 CFR Part 416

To Whom it May Concern:

I am an owner and a general surgeon of an ASC and I am writing a letter of comment regarding laparoscopic cholecycstectomies and other laparoscopic procedures relating to the interim final rule for the update of the ambulatory surgical center list of covered procedures. Most ambulatory surgery centers have a proven track record for many years of extremely low complications in all procedures and very high patient satisfaction. Their laparoscopic surgeons are very well trained in these procedures and utilize strict patient selection criteria to choose patients who are appropriate candidates for these surgeries at ASC's. The outcomes have been better than that at most hospitals because of their strict guidelines and emphasis on patient safety at Southwestern Ambulatory Surgery Center (SWASC), located in Pittsburgh, PA.

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Sincerely,

Philip P. Ripepi, M.D.

Philip P. Ripepi, M.D.
Medical Director
Southwestern Ambulatory Surgery Center

July 1, 2005

VIA HAND DELIVERY

JUN 28 2005

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1478-IFC - Medicare Program; Update of Ambulatory Surgery Center List of Covered Procedures

Dear Dr. McClellan:

On behalf of the Surgery Division of HealthSouth Corporation, I am pleased to submit the following comments regarding the interim final rule that makes revisions to the current list of Medicare approved ambulatory surgical center (ASC) procedures. 70 Fed. Reg. 23690 (May 4, 2005). The effort put forth by the Centers for Medicare and Medicaid Services (CMS) in issuing the interim final rule in a timely manner is very much appreciated.

With 176 ASCs in 36 states, HealthSouth is the largest operator of ASCs in the United States. ASCs offer a convenient, safe environment characterized by superior care, which is highly valued by both beneficiaries and their physicians.

I. Analysis of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of this Interim Final Rule with Comment Period.

A. General Comments

HealthSouth is supportive of CMS's plans to reform the ASC payment system so that it more closely resembles the outpatient prospective payment system. Designing a system that incorporates a significant expansion of the number of payment groups will greatly improve the opportunity to reimburse ASCs accurately, and if the range of payment amounts is expanded, Medicare beneficiaries may see improved access to a broader scope of services.

As you indicated in your May 12, 2005 testimony before the House Committee on Energy and Commerce, the variation in payment for the same service across the different reimbursement systems has the potential to create incentives to seek reimbursement outside the

ASC payment system. We therefore support a revised system of ASC payments, one that more accurately reflects the costs of the resources used in rendering ASC services. HealthSouth stands ready to assist CMS in your efforts to examine and refine the ASC payment system. We have a substantial database representing a broad spectrum of ASC patient case mix and services, and where it is feasible to do so we will share this data with you to facilitate your work in this area.

We believe that such systematic reform will result in several important outcomes: Medicare beneficiaries will enjoy greater access to care requiring a facility setting, and at a lower cost; the Medicare program will enjoy significant cost savings; and physicians will have greater opportunity to take advantage of the efficiencies and quality of care offered by ASCs.

In the near term, we recommend that CMS revise its general criteria for inclusion of procedures on the Medicare ASC List of Covered Surgical Procedures to reflect current trends in outpatient procedural practice and to allow beneficiaries to access care in a more intensive setting when medically necessary. In the proposed rule issued in the Federal Register on June 12, 1998, HCFA proposed to remove the references to "commonly performed" found in Section 416.65(a) in response to the consensus of comments received regarding this matter from stakeholders in the ASC community. Those changes are needed now more than ever to update and restore the relevance of the criteria CMS uses to determine which procedures are appropriately performed in the ASC. Although we anticipate reform of the ASC payment system in the near term, action taken now to revise this criterion would result in immediate and significant cost savings.

B. Proposed Deletions

HealthSouth applauds CMS's decision to forgo implementing the majority of the proposed deletions in response to public comment.

We support CMS's commitment to protecting access to safe and appropriate care for Medicare beneficiaries. Retaining virtually all of the procedures proposed for deletion will allow ASCs to continue to serve as a site of service option for those beneficiaries who, for a variety of reasons, require access to more intensive services than those typically available in the physician office.

As an alternative to the hospital outpatient setting in these circumstances, ASCs can now continue to allow the Medicare program to realize ongoing cost savings – savings that are also shared by beneficiaries in the form of reduced coinsurance payments.

C. Proposed Additions

HealthSouth appreciates CMS's addition of sixty-five procedures to the ASC list. However, we believe that the payment group assignment for certain of these procedures is insufficient to cover costs. Assigning a service to a payment group that offers insufficient reimbursement essentially nullifies the addition of that procedure to the ASC list.

Therefore we urge CMS to reconsider the payment group assignment for the following services:

1. CPT codes 36475 and 36476, which describe radiofrequency endovenous ablation of incompetent veins. CMS has proposed to assign these services to payment group 3 ($510.00). This payment group assignment is similar to the payment group assignment for traditional surgical treatments for incompetent veins. However, the resources used in performing this type of procedure are not similar to those used in traditional procedures. Significant capital equipment investment is required. The cost of just one of the supplies needed (the catheter/introducer) is approximately $800, which alone exceeds the proposed reimbursement (Closure System, VNUS Medical Technologies). We believe these procedures should be assigned to payment group 9 ($1339.00). At this reimbursement level, CMS would still realize savings - the reimbursement offered to HOPDs for the same services is in excess of $1500.

2. CPT codes 36478 and 36479, which describe laser endovenous ablation of incompetent veins. CMS has proposed to assign these services to payment group 3 ($510.00). Again, this payment group assignment is similar to the payment group assignment for traditional surgical treatments for incompetent veins. However, the resources used in performing this type of procedure are dissimilar to the traditional procedures. Capital investment in special equipment is required. Just one of the supplies needed to perform the case (the EVLT kit) costs $360 (EVLT, Diomed). We believe these procedures should be assigned to payment group 9 ($1339.00). At this reimbursement level, CMS would still realize savings - the reimbursement offered to HOPDs for the same services is in excess of $1500.

3. CPT code 46947, which describes stapled hemorrhoidopexy. This procedure has been assigned to payment group 3 ($510.00). The resource use for this procedure is not similar to the other surgical procedures for the treatment of hemorrhoids currently on the ASC list, which are assigned to payment group 3. The average cost of the disposable stapler, which is key to the performance of this procedure, is $400 (PPH, Ethicon Endo-Surgery). We believe that the procedure should be reassigned to payment group 7 ($995.00). Under OPPS, HOPD reimbursement for this procedure is in excess of $1300, so the Medicare program would still realize significant cost savings for this procedure in the ASC setting at a group 7 reimbursement level.

4. CPT code 46706, repair of anal fistula with fibrin glue. This procedure has been assigned to payment group 3 ($510.00). The resource use for this procedure differs from the resources used for the other surgical treatments for anal fistula currently on the ASC list, many of which are assigned to payment group 3. The use of fibrin glue results in additional cost of about $100 for each milliliter of glue required (Tisseel VH, Baxter Healthcare). In light of this, we suggest that the payment group assignment for this procedure should be a group 4 ($630.00). This still offers CMS tremendous cost savings as compared to the HOPD setting, where reimbursement exceeds $1300.

5. CPT code 58970, retrieval of oocyte. CMS has proposed to assign this procedure to payment group 1 ($333.00). This assignment appears to have been made based on the belief that resource use for this procedure is similar to that for CPT codes 58974 and 58976, however

the procedures are not comparable. Even under OPPS, CPT code 58970 is not in the same APC as CPT codes 58974 and 58976, implying that the significant variation in costs associated with these different procedures has been recognized elsewhere. We believe that CPT code 58970 is more appropriately assigned to payment group 7. Again, this level of reimbursement still affords cost savings as compared to OPPS payments to HOPDs for the same service.

If CMS does not revise the payment group assignments for these procedures to reflect real ASC costs, the addition of these procedures to the ASC list will have little practical effect. Beneficiary access to these services will not change, and CMS and its beneficiaries will not be able to take advantage of the cost savings typically afforded by ASCs in comparison to HOPDs.

Several of the procedures proposed for addition involve the use of implants and devices which, under 42 CFR §416.61, should be eligible for separate payment. However, the reality is that ASCs have difficulty securing separate payment for implanted devices from Medicare carriers. Medicare carriers appear to exercise a good deal of discretion related to the separate reimbursement of implanted devices placed in conjunction with an ASC covered procedure. Many carriers have published their own policies that vary widely in the scope of their coverage. In practice, ASCs are only likely to secure reimbursement for those items that a carrier has specifically indicated in writing are reimbursable in the ASC setting.

In order for the payment group assignments proposed by CMS to be considered adequate, ASCs must be assured of receiving separate reimbursement for the implants and devices associated with the procedures that require their use. This issue affects the following proposed additions:

1. Procedures involving the placement of pacemaker pulse generators, CPT codes 33212 and 33213. At this time, the only HCPCS Level II codes that specifically describe the devices placed during these procedures are C codes. C codes are only payable under the Outpatient Prospective Payment System. As a result, ASCs will have to use non-specific HCPCS codes when reporting these devices on claims. Typically the use of an unlisted HCPCS Level II code on a Medicare claim leads to denial of reimbursement. These services cannot reasonably be offered in an ASC unless ASCs can be certain that carriers will provide separate reimbursement for these expensive devices.

2. CPT codes 44397, 45327, 45345 and 45387, which describe lower gastrointestinal endoscopies in which a stent is placed. These procedures have been assigned to group 1 ($333.00), which is not sufficient to cover the cost of the stent. The cost of a colonic wall stent is not insignificant. At this time, there is no specific HCPCS Level II code that describes gastrointestinal stents, which raises the level of uncertainty regarding the receipt of reimbursement. ASCs must be assured of separate payment for the stent in order to adequately cover both the cost of the stent and the typical facility expenses related to the performance of the endoscopy itself. Under OPPS, these same procedures are classified into a separate APC that recognizes the additional costs of these devices. We believe that this same consideration of legitimate costs should be extended to ASCs.

3. Insertion of an intraperitoneal catheter as described by CPT code 49419. CMS has proposed to reimburse this procedure as a group 1 ($333.00). In order for the proposed payment group assignment to be adequate, Medicare carriers must reimburse ASCs separately for the catheter, as described by A4301. To date, Medicare carriers have reimbursed this item at their discretion, so ASCs are not assured of separate reimbursement. This is not true of reimbursement under OPPS, where payment for the device has been factored into the APC payment amount resulting in reimbursement of over $1400, with an estimated device related portion of $392.34.

4. Correction of stress incontinence with a sling operation, as described by CPT codes 51992 and 57288. Both services have been assigned to payment group 5 ($717.00), which is not sufficient to cover the cost of the material used as the sling in this type of procedure. There is no specific HCPCS Level II code for this type of implant. ASCs must receive separate reimbursement for the sling in addition to the reimbursement for the procedure itself in order to cover the costs of offering this service. The device related portion of the APC payment for 57288 under OPPS is $740.95, more than the total proposed reimbursement for ASCs.

5. Hysteroscopic sterilization as described by CPT code 58565, which requires the use of microimplants. CMS has proposed to reimburse this procedure at a group 4 ($630.00). At this time there is no specific HCPCS Level II code available to describe the microinserts, which represent a significant additional cost (approximately $1100) to the ASC. If ASCs are to offer this procedure, they must be assured of receiving separate reimbursement for these items in addition to the reimbursement for the procedure itself. The current national payment rate under OPPS for this service, which includes payment for the procedure and the implants, is in excess of $2200.

6. Procedures involving the placement of neurostimulators, such as CPT codes 64561 and 64581, describing implantation of sacral nerve stimulator electrodes. The group 3 reimbursement proposed by CMS will be adequate only if Medicare carriers provide separate reimbursement for the associated HCPCS Level II codes A4290 and E0752, which describe the test leads/electrodes, in addition to the procedure itself. Again, under OPPS the device related costs of these procedures are recognized and accounted for in structuring reimbursement.

7. Procedures for ocular surface reconstruction, such as CPT codes 65780 and 65781, which require the use of tissue transplants or grafts. Only the amniotic membrane has a specific HCPCS Level II code (V2790); limbal stem cell allograft tissue would have to be reported with a non-specific code. ASCs need to be assured that Medicare carriers will consistently reimburse these items when provided in conjunction with their associated covered services if medical necessity requirements are met.

8. Correction of lagophthalmos with the use of a lid load, CPT code 67912. Implants such as gold weights do not have a specific HCPCS Level II code, again calling into question whether the ASC will receive separate reimbursement for the lid load in addition to payment for the covered procedure.

In summary, for the above-listed services, the payment group assignment proposed by CMS will prove inadequate unless ASCs can be assured of separate reimbursement for the implants and devices required for the successful completion of these procedures. We recommend that CMS instruct carriers to provide separate reimbursement for these items, so that coverage is consistent and not subject to carrier discretion when provided in association with a medically necessary ASC covered service.

D. Procedures Rejected for Addition

In addition to the services that CMS originally proposed for addition to the ASC list, commenters recommended that numerous other procedures be added to the ASC list. Many of these requests were rejected. We believe several of these should be reconsidered.

1. Rejection on the basis of being commonly performed in the physician office.

In this interim final rule CMS cited a number of factors it found persuasive in influencing its decision to rescind the proposed deletions even though they are commonly performed in the physician office. In recognizing that deletion of these procedures would eliminate ASCs as an option to hospital outpatient departments, CMS agreed with commenters who expressed concerns regarding the impact on beneficiary access and the impact on costs to the Medicare program and its beneficiaries.

Although these arguments regarding access and cost were articulated in response to the issue of proposed deletions, we believe these same arguments apply to those services suggested for addition by commenters, but that were rejected on the basis that they are commonly performed in the physician office. In other words, we maintain that failure to add clinically appropriate services to the ASC list has the effect of limiting beneficiary access and increasing costs to both the Medicare program and its beneficiaries.

The criteria currently in use are intended to prevent the inappropriate shift of services from one clinical environment to another. However, we submit that these restrictive criteria are not only burdensome, but also unnecessary. In this interim final rule CMS presented Medicare site of service data demonstrating that inclusion of certain services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs. In fact, the data suggests that physician selection of the ASC setting is rather consistent and driven by the medical needs of patients.

The same factors that drive physicians to periodically elect the ASC as the most appropriate site of service for procedures commonly performed in the office - including those procedures that CMS decided to retain on the ASC list - will drive procedures that CMS has rejected for addition on the basis that they are commonly performed in the office setting into the generally more costly hospital outpatient department when the office setting is insufficient.

Clearly there are beneficiaries whose comorbidities make general anesthesia, or access to specialized staff, or availability of emergency equipment, or a sterile environment essential to safe care. Failing to add services that could be safely performed in the ASC to the ASC list

because they are commonly performed in the physician office adversely impacts beneficiary access for a wide range of services, and incurs greater costs than necessary by forcing more complex cases to the hospital outpatient department. Indeed it is the beneficiaries most at risk – those with comorbidities – that are most likely to face limited access and the increased coinsurance payments that result from this criterion.

Significant benefits result from allowing ASCs to serve as an alternative to hospital outpatient departments when the physician office is not sufficient to meet the legitimate medical needs of certain beneficiaries. In light of this, HealthSouth urges CMS to reconsider those additions.

2. Rejection of laparoscopic cholecystectomy on the basis of periodic need for conversion to an open procedure.

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. CMS rejected these on the basis that there is "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." 70 Fed. Reg. at 23700. CMS asserted that if an open procedure were required that the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. We are aware of only one recent study that exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of Surgery in September of 2002. In this retrospective analysis of 200 procedures, no patient required conversion to an open cholecystectomy.

When the surgeon contemplates performing an ambulatory elective laparoscopic cholecystectomy, he or she may be rigorous in the application of patient selection criteria, thereby minimizing the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Furthermore, we do not believe that the patient would have to be transported to the hospital for the open procedure if the laparoscopic attempt at an ASC were unsuccessful. If unsuccessful, the laparoscopic procedure could be converted to an open procedure and completed at the ASC. The patient would be transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient selection criteria would make this a rare occurrence.

We encourage CMS to reconsider its decision regarding laparoscopic cholecystectomy with particular attention to data that evaluate conversion rates in the ambulatory setting.

3. Rejection on the basis of being furnished as inpatient procedures most of the time and requiring more than 4 hours of recovery time.

Commenters suggested the addition of CPT code 58356, which describes endometrial cryoablation with ultrasound guidance. CMS rejected this procedure on the basis that it is furnished as an inpatient procedure most of the time and requires more than 4 hours of recovery time. We believe that CMS inadvertently grouped this procedure, which is commonly performed in the outpatient setting, with the CPT codes for vaginal hysterectomy, which are very different services.

Endometrial cryoablation is commonly performed in the ambulatory setting. A paracervical block is typically administered for anesthesia, although IV sedation may be offered to selected patients. Procedure time is under 30 minutes and the patient typically spends 1 to 2 hours in recovery following the procedure before going home.

We believe that this is an appropriate procedure for the ASC setting and request CMS to reevaluate its decision.

4. Rejection on the basis of being a radiologic study without intervention.

Several commenters requested the addition of CPT codes 62290 and 62291, which describe injections for discography of various regions of the spine. CMS rejected this suggestion stating that these procedures are radiologic studies that do not include an intervention.

While it is true that CPT codes 62290 and 62291 may be used to describe a radiologic service in conjunction with CPT codes 72285 and 72295, these codes may also be used to describe provocative discography. This is a diagnostic procedure that can provide useful information in patients suspected of having discogenic neck or back pain. The physician inserts a needle into the nucleus of the intervertebral disc under fluoroscopic guidance and injects a small amount of contrast material. Normally such an injection causes a sensation of pressure; provocation of pain that is similar to the patient's symptomatic neck or back pain suggests that the disc may be the source of that pain. Formal imaging is typically performed following the injection to allow evaluation for any anatomical changes. In other words, the injection itself, exclusive of any subsequent imaging, may provide useful clinical information when attempting to establish a diagnosis.

Because CPT codes 62290 and 62291 may be used to describe this provocative diagnostic injection procedure, these codes should not be viewed strictly as a radiologic service, but also as an important diagnostic tool in the hands of a pain management specialist.

There are many diagnostic injection procedures currently included on the ASC list that do not include a therapeutic intervention, including but not limited to CPT code 31656 describing bronchoscopy with injection of contrast material for segmental bronchography, CPT code 61055

describing cisternal or lateral cervical puncture with injection for diagnosis or treatment, and CPT codes in the 62310-62319, 64470-64476 and 64479-64483 series describing injections that may be either diagnostic or therapeutic in nature. We believe therefore that CPT codes 62290 and 62291 are appropriate additions and urge CMS to reconsider its decision.

5. Rejection on the basis of being part of another procedure.

A commenter requested the addition of HCPCS Level II code G0289. This recommendation was rejected on the basis that G0289 is part of another procedure and not performed as a separate procedure. G0289 is an "add-on" code that was specifically created by CMS to allow the appropriate reporting of these services in addition to the code for the primary arthroscopic knee intervention when certain criteria are met.

While it is true that G0289 cannot be correctly coded separately from the principal arthroscopic procedure, it is not the case that G0289 does not reflect the use of additional time and resources. In fact, CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. We believe that the use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to reconsider and add G0289 to the ASC list.

CMS also rejected several CPT codes suggested for addition on the basis that they were not provided as a separate procedure. While it is true that CPT codes 13153, 19295, and 19297 are CPT add-on codes and not reported separately, we disagree that these procedures are included in another procedure and that the facility costs for the additional work are insignificant. All three of these codes are eligible for additional facility reimbursement under OPPS.

While CPT add-on codes may never be reported independently, it is not the case that the additional work and resources represented by these codes are insignificant. By definition, CPT add-on codes describe procedures that are always performed in addition to the primary procedure, but that involve work on additional anatomic sites or additional area, a special circumstance under which a specific procedure is performed in conjunction with the primary procedure, or an additional segment of time. The current ASC list contains 38 CPT add-on codes.

CPT add-on code 13153 recognizes the additional work and resources required to perform complex repairs of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent.

CPT add-on code 19295 recognizes the additional work and resources required to perform percutaneous image-guided placement of a localization clip during the same session as a breast biopsy. Additional operating room time, additional use of imaging equipment and additional supplies (including the clip) are required to accomplish this procedure in conjunction with a breast biopsy.

CPT add-on code 19297 recognizes the additional work and resources required to place a radiotherapy afterloading balloon for breast brachytherapy during the same operative session as a partial mastectomy. The additional time in the operating room is significant. Additional supplies (including the balloon) and use of imaging equipment are needed to perform this procedure following the completion of the partial mastectomy.

We believe CMS should reconsider its decision and add these CPT codes to the ASC list.

6. Rejection on the basis of not having a CPT Category I code.

A commenter requested the addition of CPT Category III code 0020T to the ASC list. This suggestion was rejected on the basis that this procedure is not described by a CPT Category I code. We are not aware of any requirement that a procedure be described by a CPT Category I code in order to be included on the ASC list. There are currently three procedures – G0105, G0120 and G0260 - that are not CPT Category I codes, yet included on the ASC list. These services are described by HCPCS Level II G codes, which are by definition temporary codes for which there are no CPT codes.

We believe CMS should reconsider its decision, as this is a procedure that is appropriately offered in the ASC setting.

7. Rejection without articulation of a specific reason.

Commenters suggested the addition of CPT code 21386, Open treatment of orbital floor blowout fracture; periorbital approach. No reason for not adding this procedure was provided in this interim final rule. We respectfully request that CMS reconsider its decision for not adding this procedure to the ASC list or, alternatively, articulate a reason for not doing so.

E. Other Appropriate Additions Not Addressed in the Interim Final Rule

This year the American Medical Association created a new CPT code, 43257, for thermal treatment of the lower esophageal sphincter during EGD. We believe that this endoscopic treatment for gastroesophageal reflux disease is an appropriate addition to the ASC list. We suggested the addition of this procedure in our comments in response to CMS-1478-P, but it was not addressed in this interim final rule and may have been overlooked. We ask that CMS add this procedure to the ASC list.

II. Summary of Recommendations

HealthSouth is pleased with CMS's proposal to include additional procedures on the ASC list. However, there are several payment group assignments that need to be reexamined in light of different resource use and associated costs. Similarly, many of the services that CMS has proposed for addition require the use of expensive devices and implants for which ASCs must receive separate reimbursement if the payment group assignments are to be considered adequate.

We also believe that many of the additions that were proposed by commenters but not adopted by CMS deserve reconsideration. We also ask that CMS consider the addition of CPT code 43257.

Finally, we urge CMS to support policies that will both align facility payments for comparable services across different settings and abandon the current lists of site-appropriate services in favor of physician determination of the appropriate site of service.

This two-pronged approach will remove incentives for inappropriate site selection and allow physicians to determine where to render a service based strictly on the individual needs of the patient. This, in turn, is likely to lead to cost savings for the Medicare program and its beneficiaries, as ASCs have demonstrated a consistent ability to deliver high quality care at reasonable reimbursement rates.

Thank you for considering our comments. If you have any questions or need additional information, please contact me.

Sincerely,

Kimberly L Wood, MD

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AMERICAN ACADEMY OF OPHTHALMOLOGY
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Federal Affairs Department

June 22, 2005

via Electronic Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1478-IFC (Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule with Comment Period)

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the 2005 interim final Ambulatory Surgical Center rule. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the proposed rule.

We would first like to commend CMS's decision to keep several ophthalmology procedures that were identified for deletion in the proposed rule. These codes include: 11444, 11446, 11644, 13131, 13132, 13150, 13151, 13152, 14000, 14040, 14041, 14060, 14061, 68340, and 68810. The Academy is pleased that CMS considered out comments in deciding to keep these routinely utilized procedures on the list of ASC approved procedures. The Academy was also very pleased with CMS's decision to expand the list to include several additional ophthalmology procedures that were previously not approved for use in the ASC setting. Inclusion of these procedures will provide Medicare beneficiaries with expanded and safer treatment options.

The Academy was pleased with many of the changes regarding the addition and retention of procedures on the ASC list. However, we were disappointed by CMS's failure to include several other procedures referenced in our January comment letter. The Academy's comments will address our concerns regarding CMS's decision to not include these procedures on the final ASC procedure list.

Analysis of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of this Interim Final Rule with Comment Period

The Academy's January 2005 comment letter to CMS regarding the proposed ASC list asked that 66990 (use of ophthalmic endoscope) be added to the list of approved procedures. We respectfully disagree with the decision to not add 66990 to the ASC list. The interim final rule states, "CPT code 66990 does not represent a surgical procedure, and we do not believe it is an appropriate addition to the ASC list." see Fed. Reg., Vol. 70, No. 85 p. 23704 (May 4, 2005). The rule goes on to state that "The code is used to

recognize the use of equipment that is integral to surgical procedures." id. The Academy respectfully disagrees with CMS's findings regarding this code. 66990 code is an add-on CPT code for a specific endoscopic surgical approach and therefore is surgery. It is reported in conjunction with many ophthalmic surgical services which are allowed in the ASC setting. The code is never reported alone. Exclusion of this code from the approved procedures list will prevent many ophthalmogical surgical services from being performed in the ASC setting, necessitating their being performed in either the hospital out-patient department or inpatient setting at substantially greater cost to the Medicare program. The Academy strongly urges CMS to reconsider adding procedure code 66990 to the list of ASC approved procedures.

The Academy also disagrees with CMS's decision to continue excluding refractive surgical services, such as 65771 (radial keratotomy) from the ASC list because they are not Medicare covered benefits. The interim final rule states, "Radial keratotomy is not a Medicare-covered procedure and will not be added to the Medicare ASC list." see Fed. Reg., Vol. 70, No. 85 p. 23703 (May 4, 2005). Many ASCs follow Medicare rules, without exception, for other payors. Excluding procedures such as 65771 from the list makes provision of patient care more difficult for providers who would like to offer their patients the option of receiving treatment in an ASC setting. Including 65771 on the list of ASC approved procedures will simplify the work of providers at no cost to the Medicare program and will create better treatment alternatives for patients. Therefore, we would greatly appreciate your reconsideration of the Academy's request to add 65771 to the list of ASC approved procedures.

Lastly, the Academy would continue to urge CMS to consider replacing the current ASC procedure list with an exclusionary list and to expand the ASC payment groups to allow patient access to a broader range of procedures that can be performed in a more safe and cost efficient manner in this setting.

Conclusion:

The Academy would once again like to thank CMS for providing us with the opportunity to comment on the interim final rule regarding the ASC covered procedures list. We are hopeful that CMS will give immediate consideration to and act on the changes we have recommended regarding the addition of CPT procedure codes 66990 and 65771 to the list. We also encourage CSM to act to create an exclusionary procedure list and to expand the current ASC payment groups. We look forward to CMS's response to these comments.

Sincerely,

Michael X. Repka, M.D.
Secretary of Federal Affairs

National Kidney Foundation®

Making Lives Better

June 29, 2005

JUN 29 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
PO Box 8017
Baltimore, MD 21244-8017

Dear Sir or Madam:

I appreciate the opportunity to respond on behalf of the National Kidney Foundation (NKF), and its 50,000 patient and professional members, to the Interim Final Rule, "Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures,"CMS-1478-IFC, which was published in the ***Federal Register*** on May 4, 2005.

NKF urges CMS to restore CPT codes 35475 and 35476 to the list of Medicare approved additions to reimbursable Ambulatory Surgical Center procedures. CMS should not reverse the decision to include these codes, evidenced in the Proposed Rule (***Federal Register***, November 26, 2004), based on a single comment, when there is ample evidence that these procedures can be performed safely and economically in a variety of outpatient settings. Furthermore, the term "major vessel" should be narrowly construed. In fact, there is precedent for the principle that the term "major vessel" can be limited to the vena cava and the aorta. Finally, utilization of these codes could enhance quality of care and quality of life for dialysis patients.

Patients with kidney failure need to receive dialysis treatments three times a week in order to survive. For dialysis to be effective, it is necessary to provide vascular access sites and to keep those sites functional. Unfortunately, these vascular access sites frequently need repair because of stenosis or blockage and vascular access repair is one of the major reasons for hospitalization of dialysis patients. Not only is vascular access repair at ambulatory surgical centers less expensive for Medicare but it is also more convenient for patients compared to in-patient care, since delays due to operating room scheduling can be avoided. In addition, dialysis patients who have arterial or venous blockage repaired at ambulatory surgical centers are less likely to miss dialysis treatments and are able to receive dialysis treatments in the ESRD facility which normally provides their care.

Thank you very much for your consideration of our stance on this important matter.

Sincerely,

David G. Warnock, MD
President, National Kidney Foundation
Professor and Director,
Division of Nephrology
Department of Medicine
University of Alabama at Birmingham

27.

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July 1, 2005

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VIA ELECTRONIC MAIL AND U.S. MAIL

Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
Room 314G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on: *Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures* (CMS -1478-IFC)

Dear Dr. McClellan:

On behalf of Endocare, Inc., I respectfully offer the following comments on the correction to the Interim Final Rule updating the Medicare Ambulatory Surgical Center (ASC) list of covered procedures. The Interim Final Rule with comment was published in the *Federal Register* on May 4, 2005, and the correction was published in the *Federal Register* on June 24, 2005. The correction notice added CPT Code 55873, *Cryosurgical ablation of the prostate*, to the list of ASC-covered procedures.

Endocare is a medical device company focused on the development and commercialization of minimally invasive technologies for tissue and tumor ablation. Our primary area of focus has been urology (prostate cancer, in particular), and our objective is to improve men's health and quality of life. Endocare manufactures a total system required to perform cryosurgery, as well as the CryoProbes used in the prostate cryosurgery procedure.

Background on Prostate Cryosurgery

In 1999, the procedure, *cryoablation of the prostate*, was assigned a CPT Code, 55873. That same year, Medicare issued a National Coverage Determination to cover prostate cryosurgery for primary treatment. Two years later, in 2001, this surgery was covered for salvage treatment.

Prostate cryosurgery is a cancer treatment that involves the placement of cryosurgical probes transperineally into the prostate. Typically, at least six (6) (and sometimes up to eight [8]) probes are used. These probes conduct argon and helium gases in a controlled freeze process that is targeted at the cancer cells in the prostate. Other cryosurgical supplies used in this procedure include temperature probes used in tandem with the CryoProbes, and a urethral warmer.

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These supplies — CryoProbes, temperature probes, and urethral warmer—are typically purchased by healthcare providers in "kits" which range in price from $4,500 to $5,000. Facilities performing this procedure must have available a technician to operate the cryosurgery equipment. Beyond this, facilities incur costs associated with operating room time, recovery room and nurse/licensed practical nurse staffing, and basic surgical supplies and medications. In our experience, the cost of performing prostate cryosurgery procedures in outpatient facilities, like hospital outpatient departments and ASCs (some private payers cover this procedure in ASCs) is approximately $9,400 per case.

For the past several years, we have collected information on hospital outpatient facility costs associated with this procedure, and we have shared it with CMS for consideration under the hospital outpatient prospective payment system. We are also willing to share this data with you as you consider an ASC payment rate for prostate cryosurgery procedures. As we mentioned earlier, our experience is that ASC have costs quite similar to hospital outpatient departments.

Payment Considerations

If prostate cryosurgery is incorporated into Medicare's ASC payment system, where other less-invasive prostate cancer treatments are offered (e.g., prostate brachytherapy), it should receive a payment amount that approximates the costs associated with performing the procedure. We note, however, that while the procedure is assigned to the highest paying category for ASC procedures (payment group 9 that has a payment rate of $1,339), this amount clearly does not come close to covering an ASC facility's costs. Given this, we are seriously concerned that this payment rate will be misconstrued by government and private payers as appropriate for this procedure.

We understand that currently there are no other, higher-paying categories in which prostate cryosurgery can be placed. Nevertheless, we believe that, if prostate cryosurgery is added to the Medicare ASC payment system without adding higher-paying categories, CMS can take other short-term steps to alleviate the shortfall in ASC reimbursement that would result from an ASC performing this procedure.

Recommendation

We suggest that physicians be permitted to bill Medicare separately for the cryosurgical supplies used in this procedure (i.e., the CryoProbes, temperature probes, and urethral warmer) while the procedure continues to be assigned to payment group 9. We also suggest that CMS review our data on hospital outpatient facility costs associated with this procedure and use it to construct a new payment group that more-accurately reflects ASC costs.

The payment approach we suggest is similar to that taken by CMS with respect to another less-invasive prostate procedure, prostate brachytherapy. In this payment approach, brachytherapy "seeds" are billed and paid under the Medicare physician fee schedule. Failure to take a similar

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payment for prostate cryosurgery would create serious incentives for providers to perform one procedure instead of another, based on the size of the payment—not the best medical interests of the patient.

Thank you, Dr. McClellan, for giving us the opportunity to comment on this proposed rule. Please do not hesitate to contact me if you have questions or require additional information.

Sincerely,

Craig T. Davenport, Pres

Craig T. Davenport
Chief Executive Officer
Chairman of the Board

c: Herb Kuhn, Director
Centers for Medicaid Management